UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

CHARLOTTE KOCOCINSKI, Derivatively On Behalf of MEDTRONIC, INC.,

Plaintiff,

vs.

ARTHUR D. COLLINS, JR., WILLIAM A. HAWKINS, GARY ELLIS, RICHARD H. ANDERSON, DAVID CALHOUN, VICTOR J. DZAU, SHIRLY ANN JACKSON, JAMES T. LENEHAN, DENISE M. O'LEARY, KENDALL J. POWELL, ROBERT C. POZEN, JEAN-PIERRE ROSSO, JACK W. SCHULER, MICHAEL R. BONSIGNORE, GORDON M. SPRENGER, WILLIAM R. BRODY, OMAR ISHRAK

Defendants,

-and-

MEDTRONIC, INC,

Nominal Defendant.

Case No.

CLASS ACTION

SHAREHOLDER DERIVATIVE COMPLAINT

JURY TRIAL DEMANDED

INTRODUCTION

1. Plaintiff brings this shareholder derivative action on behalf of Medtronic, Inc. ("Medtronic" or the "Company") against its officers and directors for breaching their fiduciary duties to the Company and violating Section 14(a) of the Securities Exchange Act of 1934 (the "Exchange Act") between November 20, 2006 and the present (the "Relevant Period").

2. Medtronic is a Minnesota corporation that manufactures medical devices, including the INFUSE Bone Graft ("Infuse") at the heart of this action. Infuse generates approximately $800 million in revenue each year for the Company.

3. Infuse is a surgically-implanted device that stimulates bone growth. The United States Food and Drug Administration ("FDA") has approved Infuse for the treatment of degenerative discs in the lower lumbar region of the spine and for the treatment of fractures of the tibia and certain facial/oral surgeries. Known as "on-label" uses, these are the only conditions for which Infuse is an FDA-approved treatment.

4. Plaintiff's claims arise from management's intentional promotion of "off-label" uses for Infuse. Off-label use is the practice of prescribing a device for an unapproved form of administration. A physician's use of a device in a manner not specifically approved by the FDA is not illegal. It is illegal, however, for a manufacturer to promote a device's off-label uses. Here, Medtronic's officers and directors caused the Company to engage in this illegal promotion such that more than 85% of Infuse sales involved off-label use.

5. Notably, in 2006, before the Relevant Period, Medtronic settled a whistleblower lawsuit with the United States Department of Justice ("DOJ"). In that lawsuit, whistleblowers alleged that Medtronic had engaged in illegal marketing and sales practices, including paying improper consulting fees to doctors to promote products from Medtronic's Spinal division, which includes Infuse. To settle the case, Medtronic paid $40 million and entered into a Corporate

Integrity Agreement ("CIA") with the Department of Health and Human Services. Among many other provisions, this CIA required Medtronic to ensure that any arrangements between Medtronic and physicians for consulting services complied with federal law. The CIA was signed in July 2006, before the Relevant Period. Nevertheless, Medtronic's officers and directors continued paying consulting physicians to promote the off-label use of Infuse.

6. Medtronic's officers and directors also caused the Company to issue false and misleading statements about the revenues derived from Infuse sales, repeatedly touting and attributing the strong sales of Infuse to continued "strong acceptance" by the U.S. medical community. But the Individual Defendants (as defined below) failed to disclose that: (a) 85% of Infuse's revenues were dependent upon off-label uses of the product; (b) off-label uses of Infuse were causing a significant and increasing number of medical complications to patients; and (c) the Company was engaging in an unlawful campaign to market and encourage off-label uses of the product in direct violation of the Corporate Integrity Agreement with the DOJ. Because of these false statements and material omissions, shareholders were led to believe that Infuse sales were stable and would continue to grow.

7. Further, while the Individual Defendants were issuing the false and misleading statements about the source of Infuse's revenues, they simultaneously caused the Company to repurchase over ***$2.8 billion*** worth of the Company's own stock at artificially inflated prices.

8. Then, on November 18, 2008, Medtronic reported poor financial results for its 2009 second quarter. The Company reported that revenue from its Spinal segment had declined to $829 million for the quarter, down $30 million from the previous quarter. Additionally, the Company disclosed for the first time that it received a subpoena from the Department of Justice related to management's promotion of off-label use of Infuse. On this news, the Company's stock declined

sharply from a closing price of $36.42 on November 17, 2008, to a closing price of $31.60 on November 18, 2008 (a 13% decline in one day).

9. Plaintiff brings this derivative action to (a) recover damages against Medtronic's officers and directors for the benefit of the Company and (b) require the Company to reform and improve its corporate governance and internal procedures to protect Medtronic and its shareholders from a repeat of the damaging events described below.

JURISDICTION AND VENUE

10. The claims asserted herein arise in part under §14(a) of the Exchange Act, 15 U.S.C. §78n(a). Jurisdiction is conferred by the Exchange Act, and supplemental jurisdiction over the state law claims is conferred by 28 U.S.C. § 1367.

11. This Court has also jurisdiction over the subject matter of this action under 28 U.S.C. § 1332(a) because the plaintiff and defendants are citizens of different states and the matter in controversy exceeds $75,000. This action is not a collusive action designed to confer jurisdiction on a Court of the United States that it would not otherwise have. The Court also has supplemental jurisdiction under 28 U.S.C. § 1367(a).

12. Venue is proper in this Court under 28 U.S.C. §1391 because nominal defendant Medtronic is headquartered in this District, and a substantial portion of the transactions and wrongs complained of in this action occurred in this District.

13. Additionally, there is at least one other action pending in this District in which Medtronic and some of the Individual Defendants in this action are also named as defendants. Accordingly, discovery and pretrial proceedings can be coordinated in this District.

PARTIES

A. Plaintiff

14. Plaintiff Charlotte Kokocinski is a current shareholder of Medtronic, was a shareholder of Medtronic at the time of the transactions and events complained of herein, and has continuously held the stock. Plaintiff is a citizen of Pennsylvania.

B. Nominal Defendant

15. Nominal Defendant Medtronic is a publicly-traded Minnesota corporation with its principal executive offices located at 710 Medtronic Parkway, Minneapolis, Minnesota, 55432. The Company's common shares are traded on the New York Stock Exchange under the symbol "MDT." As of June 27, 2011, there were 1,060,952,075 outstanding shares of Medtronic common stock

C. Defendants

16. Defendant Arthur Collins, Jr. ("Collins") served as the Chairman of the Board of Medtronic from April 2002 until August 2008. Collins served as Chief Executive Officer ("CEO") of Medtronic from May 2002 to August 2007; as President and CEO from May 2001 to April 2002; as President and Chief Operating Officer ("COO") from August 1996 to April 2001; as COO from January 1994 to August 1996; and as Executive Vice President of Medtronic and President of Medtronic International from June 1992 to January 1994. Collins resigned from the Board in August 2008. Given his control over the Company, he breached his fiduciary duties by causing the Company to (a) illegally market Infuse for off-label use; and (b) issue false and misleading statements about the source of Infuse's revenues. On information and belief, Collins is a citizen of Minnesota.

17. Defendant William A. Hawkins ("Hawkins") served as Medtronic's President and CEO from August 23, 2007 until June 2011. He also served as Chairman of the Board and CEO of Medtronic until June 2011. He served as the Company's President and COO from May 2004 until August 2007, and as Senior Vice President and President, Medtronic Vascular, from January 2002 to

May 2004. Hawkins has served as a member of Medtronic's Board of Directors from March 2007 until June 2011. During the Relevant Period, Hawkins participated in the issuance of improper statements, including the preparation of the improper press releases and SEC filings, and was quoted in and approved the issuance of the Company's false and misleading statements made to the press, securities analysts and the Company's shareholders. Given his control over the Company, he breached his fiduciary duties by causing the Company to (a) illegally market Infuse for off-label use; and (b) issue false and misleading statements about the source of Infuse's revenues. On information and belief, Hawkins is a citizen of Minnesota.

18. Defendant Gary Ellis ("Ellis") has been the Senior Vice President and Chief Financial Officer ("CFO") of Medtronic since May 1, 2005. During the Relevant Period, Ellis participated in the issuance of improper statements, including the preparation of the improper press releases and SEC filings, and was quoted in and approved the issuance of the Company's false and misleading statements made to the press, securities analysts and the Company's shareholders. Given his control over the Company, he breached his fiduciary duties by causing the Company to (a) illegally market Infuse for off-label use; and (b) issue false and misleading statements about the source of Infuse's revenues. On information and belief, Ellis is a citizen of Minnesota.

19. Defendant Richard H. Anderson ("Anderson") has served as a member of Medtronic's Board of Directors since 2002. Anderson is the current Chairperson of the Company's Compensation Committee and a member of the Nominating and Corporate Governance Committee. Given his control over the Company, he breached his fiduciary duties by causing the Company to (a) illegally market Infuse for off-label use; and (b) issue false and misleading statements about the source of Infuse's revenues. On information and belief, Anderson is a citizen of Georgia.

20. Defendant David C. Calhoun ("Calhoun") has served as a member of Medtronic's Board of Directors since July 2007. Calhoun is also a member of the Audit Committee and Finance

Committee. Calhoun was a member of the Audit Committee during fiscal years 2008, and 2009. Given his control over the Company, he breached his fiduciary duties by causing the Company to (a) illegally market Infuse for off-label use; and (b) issue false and misleading statements about the source of Infuse's revenues. On information and belief, Calhoun is a citizen of Connecticut.

21. Defendant Victor J. Dzau ("Dzau") has served as a member of Medtronic's Board of Directors since February 2008. Dzau is also a member of the Nominating and Corporate Governance Committee and the Quality and Technology Committee. Given his control over the Company, he breached his fiduciary duties by causing the Company to (a) illegally market Infuse for off-label use; and (b) issue false and misleading statements about the source of Infuse's revenues. On information and belief, Dzau is a citizen of North Carolina.

22. Defendant Shirley Ann Jackson ("Jackson") has served as a member of Medtronic's Board of Directors since 2002. Jackson is the Chair of the Company's Quality & Technology Committee and is also a member of the Finance Committee. Jackson was a member of the Audit Committee in fiscal years 2008 and 2009. Given her control over the Company, she breached her fiduciary duties by causing the Company to (a) illegally market Infuse for off-label use; and (b) issue false and misleading statements about the source of Infuse's revenues. On information and belief, Jackson is a citizen of New York.

23. Defendant James T. Lenehan ("Lenehan") has served as a member of Medtronic's Board of Directors since January 2007. Lenehan is also a member of the Finance Committee and the Quality and Technology Committee. Given his control over the Company, he breached his fiduciary duties by causing the Company to (a) illegally market Infuse for off-label use; and (b) issue false and misleading statements about the source of Infuse's revenues. On information and belief, Lenehan is a citizen of New York.

24. Defendant Denise M. O'Leary ("O'Leary") has served as a member of Medtronic's Board of Directors since 2000. O'Leary is the current Chairperson of the Company's Audit Committee and a member of the Compensation Committee. O'Leary was a member of the Audit Committee in fiscal years 2007, 2008, and 2009. Given her control over the Company, she breached her fiduciary duties by causing the Company to (a) illegally market Infuse for off-label use; and (b) issue false and misleading statements about the source of Infuse's revenues. On information and belief, O'Leary is a citizen of California.

25. Defendant Kendall J. Powell ("Powell") has served as a member of Medtronic's Board of Directors since June 2007. Powell is the Chairperson of the Nominating and Corporate Governance Committee and a member of the Compensation Committee. Given his control over the Company, he breached his fiduciary duties by causing the Company to (a) illegally market Infuse for off-label use; and (b) issue false and misleading statements about the source of Infuse's revenues. On information and belief, Powell is a citizen of Minnesota.

26. Defendant Robert C. Pozen ("Pozen") has served as a member of Medtronic's Board of Directors since 2004. Pozen is the Chairperson of the Finance Committee and a member of the Audit Committee. Pozen was a member of the Audit Committee in fiscal years 2007, 2008, and 2009. Given his control over the Company, he breached his fiduciary duties by causing the Company to (a) illegally market Infuse for off-label use; and (b) issue false and misleading statements about the source of Infuse's revenues. On information and belief, Pozen is a citizen of Massachusetts.

27. Defendant Jean-Pierre Rosso ("Rosso") has served as a member of Medtronic's Board of Directors since 1998. Rosso is also a member of the Nominating and Corporate Governance Committee and the Quality and Technology Committee. Rosso was a member of the Audit Committee in fiscal years 2007, 2008, and 2009. Given his control over the Company, he breached his fiduciary duties by causing the Company to (a) illegally market Infuse for off-label use; and (b)

issue false and misleading statements about the source of Infuse's revenues. On information and belief, Rosso is a citizen of France.

28. Defendant Jack W. Schuler ("Schuler") has served as a member of Medtronic's Board of Directors since 1990. Shuler is also a member of the Audit Committee, and the Compensation Committee. Schuler was a member of the Audit Committee in fiscal year 2007. Given his control over the Company, he breached his fiduciary duties by causing the Company to (a) illegally market Infuse for off-label use; and (b) issue false and misleading statements about the source of Infuse's revenues. On information and belief, Schuler is a citizen of Illinois.

29. Defendant Michael R. Bonsignore ("Bonsignore") was a director of Medtronic from 1999 until his retirement on August 23, 2007. Bonsignore was a member of the Audit Committee during fiscal year 2007. Given his control over the Company, he breached his fiduciary duties by causing the Company to (a) illegally market Infuse for off-label use; and (b) issue false and misleading statements about the source of Infuse's revenues. On information and belief, Bonsignore is a citizen of New Jersey.

30. Defendant Gordon M. Sprenger ("Sprenger") was a director of Medtronic from 1991 until his retirement on August 23, 2007. Given his control over the Company, he breached his fiduciary duties by causing the Company to (a) illegally market Infuse for off-label use; and (b) issue false and misleading statements about the source of Infuse's revenues. On information and belief, Sprenger is a citizen of Minnesota.

31. Defendant William R. Brody ("Brody") was a director of Medtronic from 1998 until his retirement on August 23, 2007. Given his control over the Company, he breached his fiduciary duties by causing the Company to (a) illegally market Infuse for off-label use; and (b) issue false and misleading statements about the source of Infuse's revenues. On information and belief, Brody is a citizen of California.

32. Defendant Omar Ishrak ("Ishrak") has been the Chairman and Chief Executive Officer of Medtronic since 2011. Ishrak signed and caused the Company to file the false and misleading 2011 Proxy Statement. On information and belief, Ishrak is a citizen of Minnesota

33. Anderson, Hawkins, Ellis, Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, Schuler, Bonsignore, Sprenger, Brody, and Ishrak are sometimes referred to herein as the "Individual Defendants."

FACTUAL ALLEGATIONS

A. Background

34. Medtronic is a manufacturer of medical devices and a global leader in medical technology. Medtronic conducts its business through seven operating segments: Spinal, Cardiac Rhythm Disease Management, CardioVascular, Neuromodulation, Diabetes, Surgical Technologies, and Physio-Control.

35. The Company describes its Spinal operating segment in filings with the United States Securities and Exchange ("SEC") as "a leading supplier for innovative medical devices and implants used in the treatment of the spine."

36. As reported in the Company's Annual Report for the fiscal year ended April 29, 2011, filed on Form 10-K with the SEC, Medtronic's Spinal segment is highly material to the Company's overall operations, responsible for over one-fifth of Medtronic's overall net sales each year. Spinal fusions are one of the most common types of spine surgery and the Company's biologics products have been a strong source of earnings growth for Medtronic.

37. Because of the importance of its biologics products, the Company separately reports its "Core" Spinal and "Biologics" Spinal results. Medtronic's Biologics Spinal results primarily consist of Infuse sales, which have exceeded $3.6 billion between 2002 and 2008. As a J.P. Morgan research analyst covering Medtronic noted in a report dated November 12, 2008:

> Infuse is an $800M product for Medtronic (6% of sales), having enjoyed robust growth since its initial approval in the U.S. in July 2002. In fact, it is the one piece of Medtronic's Spine business that continues to post strong double-digit growth without any issues (LTM: +16.9%). That is, until now.

B. Medtronic Settles Whistleblower Litigation With The DOJ For Illegal Marketing And Sales Practices

38. On July 18, 2006, Medtronic announced that it had entered into a settlement with the DOJ and agreed to pay $40 million to resolve two whistleblower lawsuits alleging that the Company's Spinal division had engaged in illegal marketing and sales practices, including the payment of improper consulting fees to doctors to promote its Spinal products.

39. According to the DOJ's press release accompanying the settlement, Medtronic's Spinal division paid unlawful and improper kickbacks to doctors in a number of forms, including consulting agreements, royalty agreements and lavish trips to desirable locations between 1998 and 2003, to induce surgeons to use the Company's Spinal products.

40. The DOJ settlement attempted to resolve two separate whistleblower lawsuits brought by former employees of the Company. The two whistleblower suits, one filed in 2002, *United States ex rel. [UNDER SEAL] v. Medtronic, Inc.*, Civil Action No. 02-2709, and another in 2003, *United States ex rel. Poteet v. Zdeblick*, Civil Action No. 03-2979 *("Poteet I")*, in the U.S. District Court for the Western District of Tennessee, alleged that sales and marketing practices at Medtronic's acquired Spinal business segment violated the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), *et seq.*, which prohibits individuals from offering, soliciting or making any payment or remuneration to induce business reimbursed under a federal or state health care program, and the False Claims Act, 31 U.S.C. § 3729, *et seq.*, which provides penalties for the submission of false claims to the federal government.

41. Both lawsuits were filed under seal pursuant to provisions in the False Claims Act that permit individuals to file whistleblower lawsuits on behalf of the government and to share in any

recovery. The DOJ joined in the first lawsuit, but declined to intervene in the second action under the first-to-file and previous disclosure provisions of the False Claims Act.

42. Brought by a former Medtronic in-house counsel, the first whistleblower suit alleged that Medtronic's "aggressive and illegal" sales and marketing efforts were intended to and did serve the goal of improperly inducing doctors to use Medtronic's Spinal products. The conduct alleged included, *inter alia:* (1) lucrative consulting and royalty agreements with physicians that used Medtronic Spinal products, "the true purpose [of which were] to funnel money to the physicians so that they will be induced to use [Medtronic Spinal] products;" and (2) "[l]avish all expense paid trips to fine resorts…disguised as Medical Education seminars, think tanks, or discussion groups…held in places such as Hawaii, Cancun, Alaska, Beaver Creek, Whistler, Malaysia, Amelia Island, Teton Valley, and New Orleans at Mardi Gras…[t]he purpose of these lavish trips was to induce the physicians to use [Medtronic Spinal] products." The complaint further alleged that: "Most of the illegal kickback practices described herein were begun by Sofamor Danek and continued by [Medtronic] after the acquisition. Kickbacks were the culture and way of doing business at Sofamor Danek and the company was determined to continue that culture, and did continue that culture, when Sofamor Danek became part of the Medtronic empire."

43. The *Poteet I* complaint, which was brought by a former Medtronic employee who helped arrange travel (including expense reimbursement) for numerous spinal surgeons to attend Company-sponsored events and other professional meetings, also alleged that Medtronic paid surgeons substantial fees---sometimes up to hundreds of thousands of dollars per year---for consulting services that were grossly in excess of their fair market value, entered into royalty agreements that were designed to disguise illegal remuneration, and provided doctors opportunities for lavish travel and recreational activities, including "upgraded lodging for physicians, dinners, entertainment and activities such as golf, snorkeling, sailing, fishing, shopping trips, [and] horse-

back riding" for using Medtronic products. According to the *Poteet I* complaint, the consulting agreements and other payments were illegitimate means of inducing physicians to use Medtronic products and to recommend to other physicians that they do the same.

44. As part of the DOJ settlement, Medtronic agreed to enter into a five-year Corporate Integrity Agreement with the Office of the Inspector General/Health and Human Services. As described in Medtronic's July 18, 2006 press release, the CIA implemented substantial oversight structures and procedures meant to ensure "top-level attention to corporate compliance measures." Among other things, the CIA required Medtronic to establish an electronic database to capture and manage all non-sales related transactions between Medtronic's Spinal segment and its physicians or customers, with all such transactions subject to an established set of internal controls and review processes, including monitoring by Medtronic senior management and the Company's Chief Compliance Officer.

45. In addition, in the CIA, Medtronic made several representations regarding the procedures and policies to be adopted by the Company to ensure stricter regulatory compliance and the agreement obligated Medtronic to institute a number of changes to improve oversight of its Spinal division. Perhaps most significantly, the CIA required the Company to adopt procedures to ensure that any "arrangements"---a term intended to cover doctor consulting agreements and broadly defined as engagements involving "directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; [] between [Medtronic] and any actual or potential source of health care business [e.g., doctors]"---would not violate federal law. Such procedures were to include, among other things: (1) creating a database of all existing and new or renewed arrangements; (2) tracking remuneration from Medtronic to all other parties to such arrangements; (3) tracking service and activity logs to ensure that parties to an arrangement are performing their duties under the applicable arrangement; (4) implementing procedures that ensure all arrangements are reviewed for adherence

to the Anti-Kickback Statute; and (5) regular (at least quarterly) review by the Medtronic Compliance Officer of the arrangements database along with reporting (at least quarterly) to the Medtronic Compliance Committee.

46. Although the CIA, which was signed and executed by Medtronic on July 14, 2006, did not become effective until after the dismissal of the two whistleblower actions, the CIA and the previous whistleblower and wrongful termination litigation placed Medtronic and all Individual Defendants on actual notice, before the start of the Relevant Period, of the substantial, imminent, and material risk of continuing with the lucrative consulting agreements that Medtronic previously used to promote use of its Spinal products. Indeed, the Medtronic analyst from ThinkEquity Partners LLC observed in a June 8, 2006 report that the whistleblower lawsuits would result in Medtronic curtailing its use of consulting agreements in the future, specifically noting: "[w]e understand that Medtronic is exercising extreme caution with all physician agreements going forward and we do not anticipate this becoming an ongoing issue." Yet the Individual Defendants continued to engage in these financial arrangements as they promoted and marketed Infuse for off-label applications. Ultimately, this improper promotion and marketing led to action by the FDA and DOJ.

C. The Individual Defendants Continued To Market Infuse For Off-Label Use

47. Even though Medtronic had agreed to settle allegations relating to nearly identical conduct with the DOJ for $40 million on July 14, 2006, the Individual Defendants still illegally sought to market and promote Infuse for off-label use. The Individual Defendants were motivated to engage in this illegal conduct because they knew that unless Infuse continued to be used in large numbers for off-label use, its sales---which were primarily driven by and dependent upon off-label use---would decline dramatically. Thus, undisclosed to shareholders, the lucrative "consulting" arrangements continued after the settlement with the DOJ. Consequently, off-label Infuse use increased. The Individual Defendants, while reporting growing Infuse sales throughout the Relevant

Period, failed to disclose the material risk of another adverse regulatory response from either the FDA or DOJ.

48. Infuse was approved by the FDA for very limited surgical applications. Acknowledging these limited on-label indications, the Medtronic analyst from Bernstein Research noted in a report issued November 21, 2006, that analysts were "expecting continued indication expansion (e.g., recent dental approval and likely approval for posterior lateral fusion) for Infuse to be the main driver for the spinal business in the mid-term." What this analyst and shareholders did not know was that, despite the limited FDA-approved applications of Infuse, the Individual Defendants had been continuing to drive sales from off-label indications despite the CIA and the material risk of further regulatory action. As a result of the Individual Defendants' undisclosed misconduct, the percentage of off-label Infuse usage increased over time, including after the DOJ settlement.

49. The Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA") specifically provides that the FDA has no authority to "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed [medical] device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396. Therefore, physicians are free to prescribe or use medical devices in any manner they deem medically appropriate. However, device and drug manufacturers such as Medtronic cannot actively promote products for uses not approved by the FDA. Indeed, federal law provides for significant penalties for manufacturers that promote their products in ways inconsistent with a product's labeling. Severe penalties for off-label promotion (which, in some cases, can result in fines of up to twice the amount of the gross pecuniary gain from the offense) were designed to ensure that the FDA's careful, deliberate consideration of a product's suitability for public consumption is not undermined by manufacturers seeking to circumvent that process.

50. Under the FDCA, device manufacturers can be held liable for off-label promotion when their products are deemed misbranded under the statute. A product is misbranded when the directions and indications for the unapproved uses that the manufacturer intends the product to be used for have not been included on the label. Further, a device's intended uses are evidenced by the manufacturers' conduct, not by reference to what the FDA has approved.

51. A product's intended uses can be derived from oral statements by persons speaking on behalf of a company about its product. In other words, a manufacturer is potentially liable under the statute if its aim is to have its products used in a manner inconsistent with or outside the scope of the approved label. The company's conduct and all other relevant facts and circumstances exhibiting an intent to sell its products inconsistent with or outside the scope of the FDA-approved label are examined in determining whether the manufacturer has violated federal law. Although manufacturers have recently become increasingly sophisticated and creative in devising means of off-label promotion that are harder to detect by regulators, the costs to companies guilty of such practices can be enormous. For instance, Pfizer, Inc. and Eli Lilly & Company alone recently agreed to pay a combined $3.7 billion to resolve allegations of illegal off-label marketing.

52. Any application of Infuse outside of its FDA approved usage is considered off-label. Nonetheless, the Individual Defendants caused the Company to actively promote off-label use of Infuse by providing doctors with information about other doctors using the product off-label and by having Medtronic sales force personnel in the hospital operating rooms at the time of the off-label surgeries to provide doctors with information and instruction during the actual surgeries. These practices were widespread throughout the Company, rather than isolated to particular areas.

53. The Individual Defendants concealed the Company's efforts to promote the widespread off-label use of Infuse. Medtronic provided millions of dollars in undisclosed payments to doctors (including so-called "Key Opinion Leaders") who published articles in medical journals,

delivered presentations at continuing medical education courses, and appeared at consulting engagements addressing off-label applications of Infuse, including in the cervical spine. In turn, Medtronic's sales force would direct other doctors to these consultants and Key Opinion Leaders or their written work to further drive Infuse off-label sales. Moreover, the Individual Defendants engaged in such conduct throughout the Relevant Period, even though Medtronic had recently agreed to settle a whistleblower action with the DOJ and specifically agreed that it would engage in stricter compliance with regulatory requirements regarding the sale and marketing of its devices.

54. Defendants failed to disclose to shareholders the amount of Infuse sales for off-label applications or the amount Medtronic paid to market and promote Infuse's off-label use. Consequently, the Individual Defendants reported false and misleading sales figures for Infuse because the true facts and risks related to the source of the Infuse revenues were concealed from shareholders. Unbeknownst to shareholders, Infuse sales were dependent on higher risk off-label applications and were illegally marketed and promoted.

D. Defendants Issued False And Misleading Statements About The Source of Infuse Revenues And Medtronic's Compliance With The CIA

55. The Individual Defendants made numerous false and misleading statements throughout the Relevant Period regarding Medtronic's off-label marketing and promotion of Infuse. The Individual Defendants made these statements in Medtronic's filings with the SEC, conference calls with analysts, press releases, and other public statements. In particular, the Individual Defendants failed to disclose: (a) that 85% of Infuse sales were dependent on off-label use of the product; (b) off-label uses of Infuse were causing a significant and increasing number of medical complications to patients; and (c) that Medtronic's sales force was actively marketing Infuse for off-label use in direct violation of the CIA. Thus, unbeknownst to shareholders, the Company was risking adverse regulatory actions, investigations, lawsuits, and declining sales.

56. On November 20, 2006, Defendants Collins, Hawkins, Anderson, Jackson, O'Leary, Pozen, Rosso, Schuler, Bonsignore, Brody, and Sprenger reported Medtronic's financial results for the second quarter (ended October 27, 2006) of its 2007 fiscal year in a press release filed with the SEC as an attachment to Form 8-K (the "2Q 2007 8-K"), which was signed by Defendant Ellis. Moreover, Defendants Bonsignore, O'Leary, Pozen, Rosso, and Schuler reviewed and approved the 8-K prior to the time it was issued. Indeed, they are specifically required to do so as members of the Audit Committee. The Charter of the Audit Committee requires the members of the Committee to review with management the financial information to be included in any Forms 10-K, 10-Q and 8-K. In this first full quarter of sales after Medtronic signed the CIA with the DOJ to settle whistleblower suits regarding promotional and marketing practices in its Spinal division, the Company recorded revenue of $3.075 billion and net earnings for the quarter of $681 million, or $0.59 per diluted share. The press release stated that Spinal revenue increased 16% and noted that the Biologics line, which included Infuse, contributed significantly through 33% growth. In fact, the press release specifically listed expanded use of Infuse as a Spinal quarterly highlight:

> ***Worldwide INFUSE® Bone Graft revenue grew* 36 *percent, driven by expanded surgeon adoption***. On November 9, a Food and Drug Administration (FDA) advisory panel recommended approval of INFUSE Bone Graft for use in oral maxillofacial procedures. [Emphasis added.]

57. In a Medtronic conference call at a Piper Jaffray Health Care Conference on December 1, 2006, Defendant Collins stated that ***"INFUSE, which is our recombinant human bone morphogenic protein used initially in spinal fusion, but historically we received an FDA indication for acute tibial fractures, and just recently picked up an indication for oral maxofacial [sic] indications. It is growing very well. It was up 33% last quarter, and that is without the new indication."*** (Emphasis added.)

58. On December 5, 2006, Defendants Collins, Hawkins, Anderson, Jackson, O'Leary, Pozen, Rosso, Schuler, Bonsignore, Brody, and Sprenger filed Medtronic's Quarterly Report for the

second quarter of its 2007 fiscal year with the SEC on Form l0-Q (the "2Q 2007 10-Q"). The 2Q 2007 10-Q, which was signed by Defendants Collins and Ellis, reported the same financial results set forth in the 2Q 2007 8-K. Moreover, Defendants Bonsignore, O'Leary, Pozen, Rosso, and Schuler reviewed and approved the 10-Q prior to the time it was issued. The 2Q 2007 10-Q provided additional detail about Medtronic's Spinal business and Infuse:

> Spinal and Navigation net sales for the three and six months ended October 27, 2006 were $625 million and $1.224 billion, an increase of 16% and 15%, respectively, over the same periods of the prior year.
>
> …
>
> The net sales increase for the three and six months ended October 27, 2006 in the operating segment were driven primarily by our Spinal business, which grew 16% and 15%, respectively, over the same periods of the prior fiscal year…. Spinal Biologics net sales for the three and six months ended October 27, 2006 were $178 million and $341 million, an increase of 33% and 30%, respectively, over the same periods of the prior year. ***The Spinal sales increase reflects solid growth across our portfolio of product offerings including expanded surgeon adoption of INFUSE Bone Graft….*** [Emphasis added.]

59. The 2Q 2007 10-Q also addressed the CIA Medtronic signed as part of the settlement that the Company reached with the DOJ, stating:

> During the six months ended October 27, 2006, the Company reached a settlement agreement with the United States Department of Justice which requires the government to obtain dismissal of the two qui tam civil suits and is conditional upon such dismissal being obtained. To resolve the matter, Medtronic has entered into a five-year agreement that ***further strengthens its employee training and compliance systems surrounding sales and marketing practices. The settlement agreement also reflects Medtronic's assertion that the Company and its current employees had not engaged in any wrongdoing or illegal activity.*** [Emphasis added.]

60. In addition, the Company's 2Q 2007 10-Q also contained certifications required by the Sarbanes-Oxley Act of 2002, signed by Defendants Collins and Ellis, who each certified (among other things) that the filing did "not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading." These Defendants also certified that they had "[d]esigned

such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to [Medtronic]…is made known to us" and that the "information contained in this report fairly presents, in all material respects, the financial condition and results of operations of Medtronic, Inc."

61. These statements made in the 2Q 2007 8-K, the 2Q 2007 10-Q, and the Piper Jaffray Health Care Conference were false and misleading because they did not disclose that the strong revenues from sales of Infuse relied heavily on off-label applications of the product rather than increased "surgeon adoption" or expansion of the product's use into new FDA-approved indications, nor did they disclose that the off-label usage of Infuse resulted from the Individual Defendants' undisclosed effort to illegally market and encourage off-label use of the product.

62. Further, the statements in the 2Q 2007 10-Q regarding the CIA entered into with the DOJ were false and misleading because the Individual Defendants failed to strengthen Medtronic's employee training and compliance systems. Instead, the individual Defendants continued to illegally market and encourage off-label use of Infuse throughout the Relevant Period and also encouraged the Company's sales force to promote the product for off-label uses.

63. On February 20, 2007, Defendants Ellis, Collins, Anderson, Jackson, Lenehan, O'Leary, Pozen, Rosso, Schuler, Bonsignore, Brody, and Sprenger reported Medtronic's financial results for the third quarter (ended January 26, 2007) of its 2007 fiscal year in a press release filed with the SEC as an attachment to Form 8-K (the "3Q 2007 8-K"), which was signed by Defendant Ellis. Moreover, Defendants Bonsignore, O'Leary, Pozen, Rosso, and Schuler reviewed and approved the 8-K prior to the time it was issued. The Company recorded revenue of $3.048 billion and net earnings for the quarter of $710 million, or $0.61 per diluted share. The press release also reported:

> Spinal and Navigation revenue of $629 million grew 12 percent. Spinal revenue increased 12 percent and Navigation revenue increased 7 percent. Worldwide Spinal

> revenue was driven by the Biologics product line and the CD Horizon® LEGACY™ family of products, which includes the new PEEK ROD.

64. That same day, the Company held a conference call with analysts to discuss Medtronic's third quarter earnings. During the call, Defendant Collins reiterated the results announced in the 3Q 2007 8-K:

> Compared to the third quarter of last fiscal year, revenue of $3.048 billion increased 10%, including a $55 million positive impact of foreign currency translation. Net earnings for the third quarter of $710 million translated into diluted earnings per share of $0.61. That was $0.03 above the consensus estimate.

65. Also during this call, Defendant Hawkins added additional detail about the Company's Spinal business and Infuse:

> So turning to our Spinal and Navigation business, third-quarter revenue increased 12%. Growth in our Spinal business was fairly balanced, with spinal instrumentation sales increasing 11 % and spinal biologics growing 15%....
>
> ***Spinal results were largely driven by*** the continued growth of the legacy family, ***INFUSE bone graft***, the CD HORIZON SEXTANT system, and the DIAM system internationally. [Emphasis added.]

66. Significantly, despite these strong results, Defendant Hawkins highlighted increasing competition in the Company's Spinal division, which he attributed to aggressive sales practices of smaller, surgeon-owned companies. Noting that revenue attributable to 60 of the smaller companies had doubled in the last calendar year, Defendant Hawkins stated that their success was in part, based on "business practices" which, according to Defendant Hawkins, could "***come under increasing regulatory and public scrutiny***." (Emphasis added.)

67. Furthermore, Defendant Hawkins reiterated that the Company's business strategy was to continue to develop products that required a stricter regulatory review and approval process---"a PMA rather than a 510(k) regulatory review"---and specifically noted that expanding the indications for Infuse was part of that strategy: "Another effort of ours is in the area of oral maxillofacial bone grafting, which is an important step in the expansion of indications for Infuse. This indication for

Infuse, also requiring a PMA, received a favorable FDA advisory panel recommendation last November." In other words, Defendant Hawkins contrasted Medtronic's business practices and strategy---which investors were led to believe were based on following the proper FDA approval process---with those of other smaller spinal companies, which, unlike Medtronic, Defendant Hawkins suggested, faced the threat of "increasing regulatory and public scrutiny."

68. Later during the call, in response to a question from Citigroup analyst Matthew Dodds, Defendants Hawkins and Collins emphasized the importance of Infuse to Medtronic's Biologics business:

> **Dodds:** Okay, and one last question – on the biologics, Bill, did that also slow down a little bit? Is that an anomaly there, or is it just starting to mature in the core market of spine?
>
> **Hawkins:** No, the law of big numbers – ***that's a business continues to do well***. And as you know, with the expansion we're going to get with the OMP indication and as we get amplified - I mean we think there's lots of legs for sustainable growth in that business.
>
> Collins: ***The INFUSE still grew 15%.*** And obviously some of the comps were a little bit more difficult. ***But as Bill said, one of the biggest opportunities we have is continuing to expand the indication.*** [Emphasis added.]

69. On March 6, 2007, Defendants Ellis, Collins, Anderson, Jackson, Lenehan, O'Leary, Pozen, Rosso, Schuler, Bonsignore, Brody, and Sprenger filed Medtronic's Quarterly Report for the third quarter of its 2007 fiscal year with the SEC on Form l0-Q (the "3Q 2007 l0-Q"). The 3Q 2007 10-Q, which was signed by Defendants Collins and Ellis, reported the same financial results set forth in the 3Q 2007 8-K and discussed on the conference call, and specifically noted that the "increase in net sales for the three and nine month periods was driven by strong performances in our Spinal and Navigation, Vascular, Neurological and Diabetes operating segments." Moreover, Defendants Bonsignore, O'Leary, Pozen, Rosso, and Schuler reviewed and approved the 10-Q prior to the time it was issued. The 3Q 2007 10-Q also supplied additional detail about the Company's Spinal business and the Infuse:

> Spinal and Navigation net sales for the three and nine months ended January 26, 2007 were $629 million and $1.854 billion, an increase of 12% and 14%, respectively, over the same periods of the prior year. Foreign currency translation had a favorable impact on net sales for the three and nine months ended January 26, 2007 of approximately $3 million and $6 million, respectively, when compared to the same periods of the prior year. The net sales increase for the three and nine months ended January 26, 2007 in this operating segment were driven primarily by our Spinal business, which grew 12% and 14%, respectively, over the same periods of the prior fiscal year. Spinal instrumentation net sales for the three and nine months ended January 26, 2007 were $429 million and $1.265 billion, an increase of 11% and 10%, respectively, as compared to the same periods of the prior year. Spinal Biologics net sales for the three and nine months ended January 26, 2007 were $169 million and $509 million, an increase of 15% and 25%, respectively, over the same periods of the prior year. ***The Spinal sales increase reflects solid growth across our portfolio of product offerings including expanded surgeon adoption of INFUSE Bone Graft*** and growth of the CD HORIZON LEGACY family of products, which includes our new PEEK ROD. [Emphasis added.]

70. The 3Q 2007 10-Q also addressed the CIA Medtronic signed as part of the $40 million settlement that the Company reached with the DOJ, stating:

> To resolve the matter, Medtronic has entered into a five-year corporate integrity agreement effective upon dismissal of the two suits that ***further strengthens its employee training and compliance systems surrounding sales and marketing practices. The settlement agreement also reflects Medtronic's assertion that the Company and its current employees have not engaged in any wrongdoing or illegal activity.*** [Emphasis added.]

71. On March 13, 2007, following the release of the Company's 3Q 2007 10-Q, Defendant Hawkins, who had recently been named as successor to Defendant Collins as Medtronic's CEO, participated in a Cowen and Company Annual Health Care Conference in which he announced the approval of Infuse for oral maxillofacial procedures and reiterated the impressive sales of Infuse and the Company's strategy on expanding FDA-approved indications to drive growth:

> Now some good news---you're the first to hear this, but we just recently received expanded indication for INFUSE, for the OMF indication. We are---this is something we have been working on for quite some time. It now gives us one more indication for INFUSE. This is a distinct market from where we have operated in the past.

72. Defendant Hawkins also reiterated the Company's stated business strategy of obtaining FDA approval for new indications for Medtronic's existing products to drive growth,

explaining that "One of the things that we think [] will drive growth is, in our ability to expand indications---take existing technologies and then do clinical trials to basically expand the market that we're already in," noting that one such new indication was the approval "for the oral maxillofacial indication, for Infuse."

73. Similarly, during a March 21, 2007 Lehman Global Healthcare Conference investor call, Defendant Collins reiterated the Company's purported strategy of seeking new indications to drive Infuse sales, noting the recent approval for oral maxillofacial indications for Infuse and stating that "We will enter new markets in terms of ageing spine and trauma and we'll continue to build on Infuse applications."

74. The statements made in the 3Q 2007 8-K, the 3Q 2007 10-Q, the third quarter 2007 earnings conference call, the Cowen and Company Annual Health Care Conference, and the March 21, 2007 Lehman Global Healthcare Conference were false and misleading because they did not disclose that the strong revenues from sales of Infuse relied heavily on off-label applications of the product rather than increased "surgeon adoption" or expansion of the product's use into new FDA-approved indications, nor did they disclose that the off-label usage of Infuse resulted from the Individual Defendants' undisclosed effort to illegally market and encourage off-label use of the product. Additionally, the statements regarding Medtronic's small competitors were false and misleading because they indicated that the Company was complying with the law when, in fact, the Individual Defendants were secretly marketing Infuse for off-label use, thereby increasing the risk that the Company would be exposed to increasing regulatory and public scrutiny.

75. Further, the statements in the 3Q 2007 10-Q regarding the CIA entered into with the DOJ were false and misleading because the Individual Defendants failed to strengthen Medtronic's employee training and compliance systems. Instead, the Individual Defendants continued to illegally

market and encourage off-label use of Infuse throughout the Relevant Period and also encouraged the Company's sales force to promote the product for off-label uses.

76. On May 22, 2007, Defendants Ellis, Collins, Hawkins, Anderson, Jackson, Lenehan, O'Leary, Pozen, Rosso, Schuler, Bonsignore, Brody, and Sprenger announced Medtronic's financial results for the fourth quarter (ended April 27, 2007) of its 2007 fiscal year in a press release filed with the SEC as an attachment to Form 8-K (the "4Q 2007 8-K"), which was signed by Defendant Ellis. Moreover, Defendants Bonsignore, O'Leary, Pozen, Rosso, and Schuler reviewed and approved the 8-K prior to the time it was issued. The Company recorded fiscal year 2007 revenue of $12.299 billion, and fiscal year 2007 net earnings of $2.80 billion, or $2.41 per diluted share. The press release also reported specific revenue numbers for Medtronic's Spinal business and commented on the importance of Infuse:

> Spinal and Navigation annual revenue of $2.544 billion and fourth quarter revenue of $690 million grew 13 and 11 percent, respectively. Spinal annual revenue of $2.417 billion increased 13 percent for the year and quarterly revenue increased 10 percent. ***Spinal revenue was driven by the continued market acceptance of the InFuse product line***, the CD HORIZON LEGACY Peek Rod System and the Verte-Stack Crescent Vertebral Body Spacer. [Emphasis added.]

77. That same day, the Company conducted a conference call with analysts to discuss Medtronic's second quarter earnings. On that call, Defendants Collins and Hawkins reiterated the earnings numbers announced in the 4Q 2007 8-K:

> **Collins:** While generating $12.3 billion in revenue this past year, we were able to post a 15% annual increase in diluted earnings per share even though the year-over-year downturn in the U.S. ICD market negatively affected our performance throughout the fiscal year. As you will note, annual results exceeded the upper end of our most recent EPS---EPS guidance.
>
> …
>
> **Hawkins:** During the fourth quarter four of our business segments saw double-digit revenue growth. Vascular and diabetes each grew 22%. Neurological grew 15%. And spinal and navigation grew 11%.

78. Echoing his earlier statements in the February 20, 2007 earnings conference call, Defendant Hawkins noted that Medtronic was losing spine treatment market share to smaller competitors that, he suggested, were engaging in business practices that exposed them to potential regulatory action:

> Well, in terms of the spine, actually we lost a little bit of share in the overall spine market, and primarily due to the plethora of small surgeon-owned spine companies, which we are addressing, one, by bringing out PMA type of products, the new cervical disk, the new products like Peek Rod and Agile, so we have a clear strategy as to how to compete with those companies. And there are other things that could happen that may make it difficult for those companies going forward.

79. Analysts picked up on Defendant Hawkins' statements regarding Medtronic's competitors' sales tactics. For example, in a May 22, 2007, report, Deutsche Bank wrote that "Management noted once again that competition in the spinal implant market continues to intensify owing to market share gains of smaller players (particularly surgeon-owned companies) in light of their ***aggressive sales practices with spine surgeons."*** (Emphasis added.) In other words, Defendant Hawkins' statements conveyed the false impression-which was believed by the investor community---that the Company engaged in ethical and legal conduct, when, in fact, Medtronic had embarked on an undisclosed campaign to market Infuse for off-label uses that eventually brought about the very regulatory action he claimed would befall the Company's competitors.

80. The following day, at a May 23, 2007 Citigroup Healthcare Conference, Defendant Ellis reiterated the strong growth potential for Infuse, which Defendant Ellis described as dependent on expanding FDA-approved indications for the product, and explained that the Company's growth strategy was driven by increasing sales of products for FDA-approved indications. At the presentation, Defendant Ellis explained that "we still are operating in significantly underpenetrated markets. These graphs highlight the penetration, the people---basically, the people who are indicated for are who is getting it and the percentage of those people that are getting it. And you'll see in many of our therapies, it is very low, under 40% penetration…. So again, people that are currently

indicated that are actually receiving the appropriate therapy is very low, which means we have significant potential for the markets to continue to grow." Indeed, driving sales of Infuse for FDA-approved indications, according to Defendant Ellis, was Medtronic's strategy for increasing sales of the product, stating that "our bone morphogenetic protein, Infuse, this received FDA approval for expanded OMF indications, which we think will help grow that business going forward on the biologic side."

81. Likewise, on a May 31, 2007 conference call hosted at the Bank of America Health Care Conference, Defendant Ellis discussed Medtronic's business opportunities in the U.S., where there was significant underpenetration in many of Medtronic's markets, "which gives us more confidence that the market growth will continue to be very, very strong across those businesses." Defendant Ellis also noted that the recent FDA approval for use of Infuse in oral maxillofacial procedures "will really help reaccelerate even the biologics growth as we go into '08 and '09."

82. At a May 31, 2007 conference call hosted at the Sanford Bernstein 23rd Annual Strategic Decisions Conference 2007, Defendant Hawkins again stressed the importance of Infuse to Medtronic's business, stating that "One of the key products for us has been a biologic. We licensed a bone morphogenetic protein from Wyeth Corporation and we have been distributing that product. It has now annualizing close to I believe $600 million in sales. It's a very important product and been growing at 15% per annum." Defendant Hawkins also noted that future increases in Infuse sales would be driven by obtaining FDA approval for additional applications of the product, explaining that "We're continuing to expand the Infuse by doing clinical studies to expand the indications…." Defendant Hawkins also noted the recently-approved indication for use of Infuse for oral maxillofacial procedures, stating that "We're excited about entering [the dental market] with our or omaxillofacial [sic] indications with the Infuse and we are building a direct sales organization."

83. Similarly, at a June 13, 2007 teleconference call held as part of the Goldman Sachs 28th Annual Global Healthcare Conference, Defendant Ellis reiterated that Infuse sales would be driven by sales for FDA-approved indications, stating that "Infuse is our new-one of our big growth platforms over the last several years. We still see significant opportunity there with the expansion into [OMF] indication with Infuse. And we see increased indications with Infuse in the future." Defendant Ellis explained that the Spinal division would capitalize on underpenetrated markets and suggested that the Company would work to increase sales for FDA-approved applications, contrasting the opportunities in the Spinal division with other markets, such as pacemakers, which, "based on current indications, is closer to being fully penetrated." By contrast, "the majority of our markets, whether it is spine, diabetes, ICDs, are still not fully penetrated at all. In fact, in most cases, there are 30, 35% or even less penetration in most of those marketplaces."

84. Likewise, at a Medtronic Investor and Analyst Meeting on June 20, 2007, Medtronic's Spinal Divisions Vice President for Clinical Affairs explained that the Company's strategy for driving sales was based on obtaining FDA approval for additional applications of the Company's spinal products. Specifically, the Medtronic representative stated that:

> We know that Spine market growth over the next several years will be fueled by expanded indications and new procedural therapy…. New procedures as well as expanded indications must be supported by new innovative technologies that require rigorous clinical research to secure PMA approval.

85. The Medtronic representative specifically identified several clinical trials that the Company was sponsoring to obtain additional FDA approvals for Infuse, including an ongoing IDE trial examining the use of Infuse in off-label Posterolateral Fusions and another recently-approved IDE study involving the use of Infuse in the cervical spine. Stressing the Company's high scientific standards and its appreciation of the FDA's approval requirements, the Medtronic representative said the Company's unwillingness to "cut corners" ensured that its exposure to regulatory risk was minimized:

> We do not cut corners in clinical research, rather we do employ consistently the highest scientific standards. It allows us to reduce our regulatory risk and to generate the additional evidence required for the adoption of our devices. Our research incorporates a keen understanding of the FDA requirements and other post-approval consideration. We understand the importance of health technology assessments again worldwide and the concerns expressed by our hospital customers, payers and health policymakers.

86. On June 25, 2007, Defendants Ellis, Collins, Anderson, Bonsignore, Lenehan, Hawkins, O'Leary, Pozen, Rosso, Schuler, and Sprenger filed Medtronic's Annual Report for its 2007 fiscal year with the SEC on Form 10-K (the "2007 10-K"). The 2007 10-K, which was signed by Defendants Ellis, Collins, Anderson, Bonsignore, Lenehan, Hawkins, O'Leary, Pozen, Rosso, Schuler, and Sprenger further elaborated on Medtronic's fiscal year 2007 performance in Biologics. Moreover, Defendants Bonsignore, O'Leary, Pozen, Rosso, and Schuler reviewed and approved the 10-K prior to the time it was issued. The 2007 10-K contained additional detail about Infuse:

> Spinal and Navigation net sales for fiscal year 2007 increased by 13 percent from the prior fiscal year to $2.544 billion. Foreign currency translation of $9 million had a favorable impact on net sales when compared to the prior fiscal year. Spinal net sales for fiscal year 2007 increased 13 percent from the prior fiscal year to $2.417 billion driven by solid growth across our entire portfolio of product offerings.
>
> …
>
> Biologics net sales were $696 million in fiscal year 2007, a 22 percent increase over the prior year, ***based on continued strong acceptance of INFUSE Bone Graft.*** INFUSE Bone Graft contains a recombinant human bone morphogenetic protein, or rhBMP-2, that induces the body to grow its own bone, eliminating the need for a painful second surgery to harvest bone from elsewhere in the body.
>
> …
>
> Spinal and Navigation net sales for fiscal year 2006 increased by 19 percent from the prior fiscal year to $2.244 billion. Foreign currency translation had an unfavorable impact on net sales of $11 million when compared to the prior fiscal year. Spinal net sales for fiscal year 2006 increased 20 percent from the prior fiscal year to $2.136 billion. While this increase reflected solid growth across our portfolio of product offerings, ***Biologics net sales were $570 million, a 38 percent increase over the prior year, based on continued acceptance of INFUSE Bone Graft.*** [Emphasis added.]

87. Finally, the 2007 10-K addressed the CIA Medtronic signed as part of the $40 million settlement that the Company reached with the DOJ, stating:

> To resolve the matter, Medtronic has entered into a five-year corporate integrity agreement effective upon dismissal of the two suits that ***further strengthens its employee training and compliance systems surrounding sales and marketing practices. The settlement agreement also reflects Medtronic's assertion that the Company and its current employees have not engaged in any wrongdoing or illegal activity.*** [Emphasis added.]

88. Defendants Ellis, Collins, Anderson, Bonsignore, Lenehan, Hawkins, O'Leary, Pozen, Rosso, Schuler, and Sprenger reiterated the fiscal year 2007 financial results in Medtronic's 2007 Annual Report to shareholders. The Annual Report, which was signed by Defendants Collins and Ellis, stated the following with regard to Medtronic's financial results and the impact of Infuse on the Company's operations and financial condition:

> Spinal and Navigation net sales increased 13 percent over the prior fiscal year to $2.544 billion. ***The increase reflects strong growth across our portfolio of spinal surgery products including the INFUSE Bone Graft….***
>
> …
>
> Biologics net sales were $696 million in fiscal year 2007, a 22 percent increase over the prior year, ***based on continued strong acceptance of INFUSE Bone Graft.*** [Emphasis added.]

89. The 2007 Annual Report also addressed the CIA Medtronic signed as part of the settlement reached with the DOJ, reiterating that the "agreement reflects our assertion that ***the Company and its current employees have not engaged in any wrongdoing or illegal activity.***" (Emphasis added.)

90. The statements made in the 4Q 2007 8-K, the 4Q 2007 8-K conference call, the May 23, 2007 Citigroup Healthcare Conference, the May 31, 2007 Bank of America Health Care Conference, the May 31, 2007 Sanford Bernstein 23rd Annual Strategic Decisions Conference 2007, the Goldman Sachs 28th Annual Global Healthcare Conference, the June 20, 2007 Medtronic Investors and Analyst Meeting, the 2007 10-K, and the 2007 Annual Report were false and

misleading because they did not disclose that the strong revenues from sales of Infuse relied heavily on off-label applications of the product rather than "continued strong acceptance" or expansion of the product's use into new FDA-approved indications, nor did they disclose that the off-label usage of Infuse resulted from the Individual Defendants' undisclosed effort to illegally market and encourage off-label use of the product. Additionally, the statements regarding Medtronic's small competitors were false and misleading because they indicated that the Company was complying with the law when, in fact, the Individual Defendants were secretly marketing Infuse for off-label use, thereby increasing the risk that the Company would be exposed to increasing regulatory and public scrutiny

91. Further, the statements in the 2007 10-K and 2007 Annual Report to shareholders regarding the CIA entered into with the DOJ were false and misleading because the Individual Defendants failed to strengthen Medtronic's employee training and compliance systems. Instead, the Individual Defendants continued to illegally market and encourage off-label use of Infuse throughout the Relevant Period and also encouraged the Company's sales force to promote the product for off-label uses.

92. On September 5, 2007, Defendants Ellis, Collins, Hawkins, Anderson, Calhoun, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler filed Medtronic's Quarterly Report for the first quarter of its 2008 fiscal year with the SEC on Form 10-Q (the "1Q 2008 l0-Q"). The 1Q 2008 l0-Q was signed by Defendants Hawkins and Ellis. Moreover, Defendants Calhoun, Jackson, O'Leary, Pozen, and Rosso reviewed and approved the 10-Q prior to the time it was issued. The 1Q 2008 10-Q provided details regarding the significance of Infuse to the continued success of the Spinal segment:

> ***Spinal Biologics net sales were $190 million for the three months ended July 27, 2007, a 17 percent increase over the same period in the prior fiscal year, based on continued strong acceptance of INFUSE Bone Graft….*** Late in fiscal year 2007 we

> received FDA approval for the use of INFUSE Bone Graft for certain oral maxillofacial and dental regenerative bone grafting procedures. [Emphasis added.]

93. The 1Q 2008 10-Q also addressed the CIA Medtronic signed as part of the $40 million settlement that the Company reached with the DOJ, stating:

> To resolve the matter, Medtronic has entered into a five-year corporate integrity agreement effective upon dismissal of the two suits that ***further strengthens its employee training and compliance systems surrounding sales and marketing practices. The settlement agreement also reflects Medtronic's assertion that the Company and its current employees have not engaged in any wrongdoing or illegal activity.*** [Emphasis added.]

94. Several weeks later, on September 27, 2007, articles in the *Wall Street Journal* and *The New York Times* reported on a letter Senator Grassley sent to Defendant Hawkins requesting a briefing from the Company and documents related to Medtronic's physician payments, an inquiry that was prompted by allegations in the whistleblower action that settled just before the start of the Relevant Period and news reports that indicated the Company's physician consultants had sometimes promoted off-label use of Medtronic products. The *New York Times* article stated that "Medtronic's payments to surgeons appear to have continued for at least several months after the settlement [with the DOJ] was reached in July 2006," which itself demonstrates that the investor community had accepted Medtronic's misleading statements indicating that the Company had curbed the activities that formed the basis of the whistleblower suits. In an attempt to quell the serious concerns raised by these reports, and to continue misleading investors regarding the true facts as set forth herein, in a September 28, 2007 article in the Minneapolis-St. Paul *Business Journal*, a Medtronic spokesman stated that Medtronic's payments to doctors had been ***"fully compliant with the law and industry standards."*** (Emphasis added.)

95. The statements made in the 1Q 2008 10-Q and by the Medtronic spokesman were false and misleading because they did not disclose that the strong revenues from sales of Infuse relied heavily on off-label applications of the product rather than "continued strong acceptance" or

expansion of the product's use into new FDA-approved indications, nor did they disclose that the off-label usage of Infuse resulted from the Individual Defendants' undisclosed effort to illegally market and encourage off-label use of the product.

96. Further, the statements in the 1Q 2008 10-Q regarding the CIA entered into with the DOJ were false and misleading because the Individual Defendants failed to strengthen Medtronic's employee training and compliance systems. Instead, the Individual Defendants continued to illegally market and encourage off-label use of Infuse throughout the Relevant Period and also encouraged the Company's sales force to promote the product for off-label uses.

97. On December 4, 2007, Defendants Ellis, Hawkins, Collins, Anderson, Calhoun, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler filed Medtronic's Quarterly Report for the second quarter of its 2008 fiscal year with the SEC on Form 10-Q (the "2Q 2008 10-Q"). Moreover, Defendants Calhoun, Jackson, O'Leary, Pozen, and Rosso reviewed and approved the 10-Q prior to the time it was issued. Indeed, they are specifically required to do so as members of the Audit Committee. The Charter of the Audit Committee requires the members of the Committee to review with management the financial information to be included in any Forms 10-K, 10-Q and 8-K. The 2Q 2008 10-Q, which was signed by Defendants Hawkins and Ellis, contained detail concerning the Spinal segment and the significant role that Infuse played in the performance of that segment:

> Spinal net sales for the three and six months ended October 26, 2007 were $660 million and $1.304 billion, an increase of 10 percent and 11 percent, respectively, over the same periods of the prior fiscal year.
>
> * * *
>
> Spinal Biologics net sales for the three and six months ended October 26, 2007 were $198 million and $388 million, an increase of 11 percent and 14 percent, respectively, over the same periods of the prior fiscal year. ***These increases were primarily driven by continued strong acceptance of INFUSE Bone Graft in the U.S.*** [Emphasis added.]

98. The 2Q 2008 10-Q also addressed the CIA that Medtronic signed as part of the $40 million settlement the Company reached with the DOJ, stating:

> To resolve the matter, we have entered into a five-year corporate integrity agreement effective which will become effective when any appeals regarding those dismissals to the U.S. Court of Appeals for the Sixth Circuit become final. ***The corporate integrity agreement further strengthens our employee training and compliance systems surrounding sales and marketing practices. The settlement agreement reflects our assertion that the Company and its current employees have not engaged in any wrongdoing or illegal activity.*** [Emphasis added.]

99. The statements made in the 2Q2008 10-Q were false and misleading because they did not disclose that the strong revenues from sales of Infuse relied heavily on off-label applications of the product rather than "continued strong acceptance" from the U.S. medical community, nor did they disclose that the off-label usage of Infuse resulted from the Individual Defendants' undisclosed efforts to illegally market and encourage off-label use of the product.

100. Further, the Individual Defendants' statements in the 2Q 2008 10-Q regarding the CIA entered into with the DOJ were materially false and misleading because the Individual Defendants failed to strengthen Medtronic's employee training and compliance systems. Instead, the Individual Defendants continued to illegally market and encourage off-label use of Infuse throughout the Relevant Period and also encouraged the Company's sales force to promote the product for off-label uses.

101. On March 4, 2008, the Defendants Ellis, Hawkins, Collins, Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler filed Medtronic's Quarterly Report for the third quarter of its 2008 fiscal year with the SEC on Form 10-Q (the "3Q 2008 10-Q"). Moreover, Defendants Calhoun, Jackson, O'Leary, Pozen, and Rosso reviewed and approved the 10-Q prior to the time it was issued. The 3Q 2008 10-Q, which was signed by Defendants Hawkins and Ellis, contained detail concerning the Spinal segment, highlighting the fact that Infuse continued to be a primary driver of net sales increases in the Biologics division:

> Spinal net sales for the three and nine months ended January 25, 2008 were $808 million and $2.112 billion, an increase of 35 percent and 19 percent, respectively, over the same periods of the prior fiscal year.
>
> …
>
> Spinal Biologics net sales for the three and nine months ended January 25, 2008 were $206 million and $594 million, an increase of 20 percent and 16 percent, respectively, over the same periods of the prior fiscal year. ***These increases were primarily driven by continued strong acceptance of INFUSE Bone Graft in the U.S.*** [Emphasis added.]

102. The 3Q 2008 10-Q also addressed the CIA that Medtronic signed as part of the $40 million settlement the Company reached with the DOJ, stating:

> The two suits were based upon allegations about certain sales and marketing practices in the Spinal business. To resolve the matter, we have entered into a five-year corporate integrity agreement which will become effective when any appeals regarding those dismissals to the U.S. Court of Appeals for the Sixth Circuit become final. ***The corporate integrity agreement further strengthens our employee training and compliance systems surrounding sales and marketing practices. The settlement agreement reflects our assertion that the Company and its current employees have not engaged in any wrongdoing or illegal activity.*** [Emphasis added.]

103. The statements made in the 3Q 2008 10-Q were false and misleading because they did not disclose that the strong revenues from sales of Infuse relied heavily on off-label applications of the product rather than "continued strong acceptance" by the U.S. medical community, nor did they disclose that the off-label usage of Infuse resulted from the Individual Defendants' undisclosed efforts to illegally market and encourage off-label use of the product.

104. Further, the statements in the 3Q 2008 10-Q regarding the CIA entered into with the DOJ were materially false and misleading because the Individual Defendants failed to strengthen Medtronic's employee training and compliance systems. Instead, the Individual Defendants continued to illegally market and encourage off-label use of Infuse throughout the Relevant Period and also encouraged the Company's sales force to promote the product for off-label uses.

105. Defendants Ellis, Hawkins, Collins, Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler continued to make false and misleading statements in

Medtronic's 2008 Annual Report, which contained the Company's fiscal year 2008 financial results. The 2008 Annual Report, which was signed by Defendants Hawkins and Ellis, stated the following with regard to Medtronic's financial results, and the impact of Infuse on the Company's operations and financial condition:

> Spinal net sales for fiscal year 2008 increased by 23 percent from the prior fiscal year to $2.982 billion.
>
> ***
>
> Biologics net sales for fiscal year 2008 increased 16 percent from the prior fiscal year to $815 million. ***This increase was primarily driven by continued strong acceptance of INFUSE Bone Graft in the U.S.*** [Emphasis added.]

106. The 2008 Annual Report also addressed the CIA Medtronic signed as part of the settlement reached with the DOJ, reiterating that the "agreement reflects our assertion that *the **Company and its current employees have not engaged in any wrongdoing or illegal activity.***" (Emphasis added.)

107. The statements made in the 2008 Annual Report were false and misleading because they did not disclose that the strong revenues from sales of Infuse relied heavily on off-label applications of the product rather than "continued strong acceptance" from the U.S. medical community, nor did they disclose that the off-label usage of Infuse resulted from the Individual Defendants' undisclosed efforts to illegally market and encourage off-label use of the product.

108. Further, the Individual Defendants' statements in the 2008 Annual Report regarding the CIA entered into with the DOJ were materially false and misleading because the Individual Defendants failed to strengthen Medtronic's employee training and compliance systems. Instead, the Individual Defendants continued to cause the Company to illegally market and encourage off-label use of Infuse throughout the Relevant Period and also encouraged the Company's sales force to promote the product for off-label uses.

109. On August 19, 2008, the Company held an analyst conference call to discuss Medtronic's first quarter earnings. During this conference call, Defendant Hawkins described the competitive pressures facing the Core Spinal business and the strong performance of the Biologics unit:

> As we have described previously, although the market for Core Spine products in the US continues to grow in the low double digits, our market share position remains under pressure, primarily from the proliferation of smaller, privately-held companies.
>
> Strong performance in Biologics continued again this quarter, with growth of 16%. ***During the quarter, we announced approval to market two smaller kit sizes of INFUSE Bone Graft for use in certain spinal fusion and oral maxillofacial procedures, which helped contribute to the largest revenue quarter ever for INFUSE.***
>
> Since its market introduction, INFUSE has been successfully used to treat thousands of patients. Expanding our portfolio of INFUSE products will help broaden availability to a larger group of patients. [Emphasis added.]

110. Defendant Hawkins went on to discuss expanded indications of the Infuse (without disclosing that approximately 85% of Infuse sales at that time were already for off-label applications):

> The key to our future success in the Spinal business will be our commitment to driving long-term innovation. This commitment is reflected in the breadth of innovative products in the long-term Spinal product development and clinical pipeline, including… ***a series of expanded indications for our INFUSE bonegraft.*** [Emphasis added.]

111. Defendant Hawkins later emphasized the strength and significance of the Spinal division:

> So I mean, we are all over the Spine business right now, I can tell you. And I am confident that this business is going to be a strong business for Medtronic. And by the way, as I mentioned, **the *Biologics continues to do very well with the two new small kit sizes. You know, we have got a dedicated sales force going after the OMF marketplace, and we are beginning to see some traction there.*** So, look, I am optimistic and very confident in the Spine business. [Emphasis added.]

112. On September 3, 2008, Defendants Ellis, Hawkins, Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler filed Medtronic's Quarterly Report

for the first quarter of its 2009 fiscal year with the SEC on Form 10-Q (the "1Q 2009 10-Q"). Moreover, Defendants Calhoun, Jackson, O'Leary, Pozen, and Rosso reviewed and approved the 10-Q prior to the time it was issued. The 1Q 2009 10-Q, which was signed by Defendants Hawkins and Ellis, contained detail concerning the Spinal segment, highlighting the material role played by Infuse in the Company's performance:

> Spinal net sales for the three months ended July 25, 2008 were $859 million, an increase of 33 percent over the same period of the prior fiscal year.
>
> ***
>
> Spinal Biologics net sales for the three months ended July 25, 2008 were $221 million, an increase of 16 percent over the same period of the prior fiscal year. ***This increase was primarily driven by continued strong acceptance of INFUSE Bone Graft in the U.S. The U.S. growth was influenced by the introduction of extra small and a double extra small INFUSE kits for use in spinal and oral maxillofacial procedures. These smaller kits expand the potential user population.*** [Emphasis added.]

113. The statements made in the 1Q 2009 10-Q and the August 19, 2008 analyst conference call were false and misleading because they did not disclose that the strong revenues from sales of Infuse relied heavily on off-label applications of the product rather than "continued strong acceptance" by the U.S. medical community, nor did they disclose that the off-label usage of Infuse resulted from the Individual Defendants' undisclosed efforts to illegally market and encourage off-label use of the product.

114. Further, Defendants described the success of the smaller size Infuse kits without disclosing that they were primarily being made available in these smaller sizes not for the procedure they described, which had been approved by the FDA, but for off-label use, particularly in the cervical spine.

115. On September 5, 2008, the day after the *Wall Street Journal* published articles about complications suffered by many patients who received the Infuse in off-label applications, the Minneapolis-St. Paul *Star Tribune* quoted a Medtronic spokesperson as saying, "Infuse is a

revolutionary and safe product, when used within its current product labeling," and ***"Medtronic does not promote off-label use."*** (Emphasis added.)

116. On September 25, 2008, in response to a *Wall Street Journal* article published the same day regarding the whistleblower suits alleging improper financial relationships between Medtronic and doctors who use Infuse, Defendants Ellis, Hawkins, Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler caused the Company to issue a press release stating:

> ***Behaviors like those described in the article are inconsistent with Medtronic's ethical standards.***
>
> ***Since the* qui tam *lawsuit, the company has put more rigorous systems and processes in place to assure alignment with these standards, identify any break from standards, and address behavior that is in violation.***
>
> Employees must follow rigorous compliance processes in connection with all arrangements with physicians, including consulting and service agreements and appropriate travel and entertainment.
>
> ***
>
> Because these goals are so central to the ability of our company and our industry to steadily improve patient outcomes, we are committed to continuous improvement and will continue to take whatever actions are required, at any point in time, to remediate unacceptable conduct when it occurs, and to prevent it from occurring in the future. [Emphasis added.]

117. These statements were false and misleading because they asserted that Medtronic was not engaging in off-label promotion of the Infuse, even though the Individual Defendants were marketing and encouraging off-label use of the product throughout the Relevant Period.

E. The FDA Warns About Off-Label Use Of Infuse And Shareholders Learn Of Management's Unlawful Promotion Of Off-Label Uses

118. On July 1, 2008, the FDA issued a Public Health Notification to healthcare practitioners, entitled "Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion" (the "FDA Notification"), strongly warning

medical professionals who used Infuse and other bone growth products of serious complications that had occurred from the off-label use of these products in the cervical spine. The FDA Notification stated that the agency had received numerous reports of complications from bone growth products use in the cervical spine that "were associated with swelling of neck and throat tissue, which resulted in compression of the airway and/or neurological structures in the neck. Some reports describe difficulty swallowing, breathing or speaking." The notification further stated that these complications had resulted in "the need for emergency medical intervention," which included "respiratory support with intubation, anti-inflammatory medication, tracheotomy and most commonly second surgeries to drain the surgical site." The FDA Notification concluded that "in light of the serious adverse events described above, FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies."

119. The following day, a Medtronic analyst from ThinkPanmure noted that the FDA Notification was both a "rare" comment from the agency on off-label usage of a product and contained ***"strong language"*** that would hurt enthusiasm for off-label use of Infuse, especially in the cervical spine. The analyst noted: "***[s]eldom does the FDA make such a strong comment on the off-label usage of a product***. We think this will discourage the cervical use of BMP entirely…. We also think that this letter will make some doctors think twice about off-label usage in the lumbar spine." (Emphasis added.) Later reports echoed this observation.

120. However, the Individual Defendants' false and misleading statements during the Relevant Period obscured the warning's significance. For example, a July 4, 2008 article in the Memphis, Tennessee *Commercial Appeal* quoted an RBC Capital Markets health care analyst who said the warning letter was unlikely to affect sales of Infuse because it was limited to off-label uses. According to the article:

> Because the FDA warning focused on an off-label use, it is unlikely to affect Medtronic's sales or stock price, said Phil Nalbone, an analyst with RBC Capital

> Markets in San Francisco. "This advisory from the FDA is important for patients and doctors, but it in no way should be seen as a negative for Medtronic," he said.

121. On September 4, 2008, *The Wall Street Journal* published a front-page article entitled "Medtronic Product Linked to Surgery Problems," which discussed both the complications resulting from the use of Infuse in the cervical spine already disclosed in the FDA Notification and additional complications resulting from other off-label applications of the product. The article stated:

> The FDA's alert about Infuse was specific to neck surgeries. But a review of FDA records and medical literature shows there have been scores of other cases in which serious complications arose after the product was used in other off-label situations. Many of these cases involve unwanted bone growth near nerves or in areas outside targeted fusion sites. That can lead to pain, repeat surgeries and, in some cases, emergency intervention.

The article further stated that at least three-quarters of the adverse events reported to the FDA involved off-label use of Infuse. This news had serious implications for Medtronic because off-label use of Infuse represented a high percentage of all Infuse sales. In addition, *The Wall Street Journal* report noted ongoing whistleblower litigation against the Company related to alleged off-label promotion of Infuse, including claimed kickbacks to doctors to promote the product.

122. Thereafter, on November 12, 2008, J.P. Morgan issued the results of a proprietary survey of fifty U.S. spine surgeons that sought to gauge their expected use of Infuse following the FDA Notification and the adverse reports since the issuance of that FDA warning regarding complications from off-label use of Infuse, and the whistleblower suits alleging illegal off-label promotion through payments to doctors. J.P. Morgan's report on this survey, entitled "Infuse at Risk: Proprietary JPM Spine Survey and F2Q Preview," concluded that although Infuse had been a significant driver of growth for Medtronic and was one of the Company's most consistent products, "in the wake of an FDA warning letter on off-label use in the cervical spine, a whistleblower suit targeting leading Infuse surgeons, and a resulting increase in reimbursement scrutiny tied to off-label use, sales are starting to slow and likely [will] come in below consensus expectations over the next several quarters." J.P. Morgan further opined that cervical use of Infuse "is likely to decline

considerably" and that lumbar use would moderate in the wake of the FDA Notification and coverage of the whistleblower suits. It found that "[o]ne third of surgeons said they expect to reduce Infuse use in the wake of these events, forecasting a 57% reduction in cervical applications and 24% decline in lumbar." The surgeons as a whole forecast a 6% decline in Infuse use in the coming year, which is a significant reversal for a product that grew 16.9% over the previous year.

123. On November 14, 2008, William Blair & Company issued a report that provided additional discussion of the concerns expressed in the J.P. Morgan report, specifically regarding the effect that the FDA Notification would have on Infuse sales. The analyst noted that "Infuse had remained a bright spot with midteens growth, but ***a recent FDA warning letter likely has chilled the widespread off-label use of the product in the cervical spine***, suggesting the company will miss our target this quarter." (Emphasis added.)

124. Several days later, on November 18, 2008, in connection with reporting Medtronic's financial results for its 2009 second quarter (ended October 24, 2008), Medtronic reported that revenue from its Spinal segment had, in fact, declined to $829 million for the quarter, down $30 million from the previous quarter. The decreased sales in the Spinal segment stemmed from a significant decline in Infuse sales and were a sharp deviation from the Company's reports of repeated double-digit growth in the Spinal segment in previous quarters. Moreover, the Company disclosed, for the first time, that: ***"we recently received a subpoena from the Department of Justice looking into off-label use of Infuse."*** (Emphasis added.)

125. During the Company's quarterly earnings conference call, conducted the morning of November 18, 2008, Defendant Hawkins discussed the problems with Infuse and stated that the "***[p]ublic health notice issued on the use of bone morphogenetic protein and the cervical setting, along with the related negative press coverage and payer pushback created some significant new hurdles.***" (Emphasis added.) Defendant Hawkins then went on to describe the problems with Infuse

in more detail and added that Medtronic had received a subpoena from the DOJ looking into off-label use of Infuse:

> The biggest surprise in the quarter was the result in our biologics business where revenue of $198 million was flat. These results reflected the impact of several external factors, including the FDA public health notice regarding the cervical use of bone morph genetic [sic] protein, several negative stories from the news media and a recent whistleblower lawsuit filed against a number of spine surgeons. These issues are unfolding against a broader backdrop of increased scrutiny regarding off-label use of medical devices in general. ***In fact, we recently received a subpoena from the Department of Justice looking into off-label use of Infuse.*** [Emphasis added.]

126. In response to an analyst's question, Defendant Hawkins referred to these problems as "kind of the perfect storm." The strong FDA Notification and a subpoena from the DOJ and the numerous other negative developments noted by Defendant Hawkins were precisely the undisclosed risks that the Individual Defendants had been taking by engaging in illegal off-label promotional practices.

127. The analyst community reacted sharply to news of the Infuse sales decline and the new disclosure regarding the DOJ subpoena. Following on its previous week's warning regarding Infuse, J.P. Morgan's Medtronic analyst wrote "[s]pine sales continue to be disappointing .... *INFUSE is the latest red flag. Sales growth in the quarter was flat, reflecting increasing concerns by surgeons to use the product off label.*" (Emphasis added.) The Medtronic analyst from Morgan Stanley summarized the negative developments regarding Infuse in detail, stating: "***Spine was particularly light, and even worse than we previewed last week when we sounded the alarm on InFuse with survey. For the quarter, InFuse came in flat [year-over-year], missing Street consensus by a shocking $18M.***" (Emphasis added.) Collins Stewart's Medtronic analyst also noted the significant impact that weak Infuse sales had on Medtronic's financial results, stating "[s]pine sales continue to be disappointing…. ***INFUSE is the latest red flag. Sales growth in the quarter was flat, reflecting increasing concerns by surgeons to use the product off label.***"

(Emphasis added.) The Medtronic analyst from Morgan Stanley summarized the negative developments regarding Infuse in detail, stating:

> ***Infuse sales were flat at* $198 *million, missing our estimate of $220 million.*** This shortfall resulted from several factors including the FDA public health notice regarding the cervical use of BMP, several negative news stories from the media regarding off-label use for the cervical indication, and a whistleblower suit filed against a number of spine surgeons. Medtronic also disclosed that it recently received a subpoena from the Department of Justice seeking information into off-label use of Infuse…. ***It will be difficult for Medtronic to combat each of these threats to its spine franchise and sales in this division will continue to struggle.*** [Emphasis added.]

128. Other analysts covering Medtronic echoed Morgan Stanley in predicting that the newly-disclosed problems with Infuse would continue to plague Medtronic's sales in the near future. In a report issued following the conference call, Credit Suisse predicted that "[w]e don't think things get better from here; in fact there is a real risk things get worse." Collins Stewart noted that "[u]nderperformance in Spine is likely to continue with reduced sales from off-label use of INFUSE in cervical spine procedures." And in a report issued after the earnings conference call, J.P. Morgan's Medtronic analyst noted that "[w]e are further reducing our Biologics forecast today, now estimating a 10% decline in Infuse sales in the back half of the year and a further 3% contraction in FY10. Medtronic also announced today that it has received a subpoena from the US Department of Justice (DOJ), which will take some time to resolve and is likely in our view to put further pressure on off-label usage."

F. Additional Disclosures Reveal The Extent To Which The Company Was Improperly Marketing Off-Label Uses To Doctors And Surgeons

129. Following the Company's disclosure of the DOJ investigation and the whistleblower lawsuit against various surgeons, a series of negative news stories surfaced about Medtronic's financial arrangements with doctors and surgeons and their involvement with and promotion of off-label use of Infuse.

130. For example, a December 12, 2008 Minneapolis-St. Paul *Star Tribune* article reported on Medtronic's financial relationship with several surgeons at Twin Cities Spine Center, one of the world's largest spine practices. As noted in the article, documents filed in the Boston whistleblower action earlier that week included a July 2002 letter to Defendant Collins from one Twin Cities Spine surgeon, Dr. Ensor Transfeldt, inviting Defendant Collins to view an off-label procedure involving Infuse scheduled just days after the FDA's approval of the product. The article also discussed two other documents filed in the litigation---a 2002 draft consulting agreement providing for payments to several Twin Cities Spine surgeons of $4,000 per day not to exceed a total of $80,000 per year, for a total of $240,000 for the three-year contract term and a proposed royalty agreement for six Twin Cities Spine doctors that would provide payments of 5 percent of net sales of "royalty products" sold in the United States to compensate the doctors for their work in helping to develop or contribute to these future "inventions"---that hinted at the lucrative opportunities for surgeons who worked for the Company.

131. Subsequently, on January 16, 2009, *The Wall Street Journal* reported on a letter sent by Senator Grassley to Kevin P. Reilly, President at the University of Wisconsin, regarding the consulting and royalty payments received by Dr. Zdeblick, the Chair of the university medical school's Department of Orthopedics & Rehabilitation and one of the surgeons who authored some of the preliminary studies that led to the FDA's approval of Infuse. Although the university is required to monitor its researchers' financial conflicts of interest, according to information requested from Medtronic by Senator Grassley that he disclosed in his January 16, 2009 letter, the amounts Medtronic paid Dr. Zdeblick far exceeded those he reported to the university. Specifically, while Dr. Zdeblick was only required to disclose annual amounts in excess of $20,000 per year, and in one year reported payments in excess of $40,000, Dr. Zdeblick actually received between $2.6 million and $4.6 million per year from Medtronic, for a total of $19 million in payments, from 2003 through

2007. Similarly, Senator Grassley's inquiry into Medtronic's consulting arrangements uncovered that Dr. Jeffrey Wang of UCLA failed to disclose payments received by the Company, resulting in a university probe of his research and his removal as co-executive director of the UCLA Comprehensive Spine Center.

132. On May 13, 2009, *The New York Times* disclosed that the U.S. Army's investigation into a study authored by Dr. Kuklo concluded that the doctor made false claims that overstated the benefits of Infuse in treating wounded soldiers injured in Iraq. As reported in *The New York Times* and detailed in the Army's findings, Dr. Kuklo, a former Army surgeon who was then a professor at Washington University in St. Louis, falsified data that exaggerated the benefits of Infuse in a prominent medical journal, conduct that Col. J. Edwin Atwood, an Army doctor who led the Army's inquiry, described as "the ultimate tragedy and catastrophe in academic medicine."

133. As disclosed in a series of articles in *The New York Times* and *The Wall Street Journal*, the true facts regarding Dr. Kuklo's study were only uncovered when one of the study's supposed "co-authors," Lt. Col. Romney C. Andersen, was congratulated on its publication by a colleague. After this discovery, Andersen alerted Army investigators who found that:

- Dr. Kuklo listed four other Army surgeons as "co-authors" without their knowledge, and these four doctors did not participate in or review the article's preparation or submission for publication;
- The signatures of the four doctors listed as co-authors on the copyright release forms submitted to *The Journal of Bone and Joint Surgery* were forged by Dr. Kuklo;
- The number of cases cited by Dr. Kuklo in the article differed from the number of cases contained in the Wartime casualty database, with no explanation for the discrepancies in the article;
- Contrary to Army policy, Dr. Kuklo did not obtain publication review or clearance from Walter Reed prior to submitting the article for publication; and
- The published results of the article suggested a much higher efficacy rate for Infuse than is supported by the experience of the purported coauthors.

134. According to one of the Army's investigators, Colonel Norvell V. Coots, the study cited higher numbers of patients and injuries than the hospital could account for. "It's like a ghost population that were reported in the article as having been treated that we have no record of ever having existed," Colonel Coots said. "So this really was all falsified information." *The Journal of Bone and Joint Surgery* formally retracted the article and banned Dr. Kuklo from submitting further papers to the Journal in March 2009 after receiving correspondence from Walter Reed dated November 6, 2008 stating that its investigation concluded that Dr. Kuklo did not follow Army regulations in submitting the article, that the signatures of the purported coauthors had been forged and that the article's purported co-authors had questioned the study's findings.

135. As noted in a May 19, 2009 follow-up article in *The New York Times,* when questioned about its ties to Dr. Kuklo, Medtronic repeatedly declined to disclose when it began its financial relationship with the former Army surgeon or the extent of funding it provided. Senator Grassley, who had been leading a Congressional investigation into Medtronic's promotion of Infuse, stated that Dr. Kuklo's name did not appear on a list of paid consultants for Infuse provided by the Company that the Senator had requested in a September 30, 2008 letter to Defendant Hawkins. Senator Grassley disclosed the list Medtronic provided-which included 22 doctors who were paid a total of $943,000 from 2005 to 2008-in a May 18, 2009 letter to Defendant Hawkins that was published in the *Congressional Record* the following day. According to the May 18, 2009 letter, Senator Grassley was "concerned" that Medtronic did not provide Dr. Kuklo's name in response to his inquiry that specifically requested information regarding consultants who work on Infuse, as it was "clear that Dr. Kuklo had some sort of consulting agreement" and was named in *The New York Times* as a consultant on Infuse. Indeed, Dr. Kuklo has given numerous presentations for Medtronic about the bone-growth product over the past several years.

136. The list provided to Senator Grassley also omitted names of other Medtronic consultants who have spoken about Infuse, such as Dr. Polly, another former Walter Reed surgeon. Frustrated with the Company's omissions, Senator Grassley stated in his May 18 letter that "[i]n the future, I hope that instead of not providing me with the name of the physician involved in Infuse, or any other matter that I am looking into, that Medtronic contact me to avoid the situation in which we find ourselves." A May 19, 2009 *New York Times* article reported that Medtronic also faced a DOJ inquiry as to whether it illegally promoted uses of Infuse that were not approved by the FDA by paying doctors, among other alleged measures.

137. However, it was not until approximately one month later, on June 18, 2009, that Medtronic disclosed to *The Wall Street Journal* that Dr. Kuklo had received almost $850,000 in payments from the Company over the past 10 years, the majority of which---nearly $800,000---were made in the past three years when Dr. Kuklo was shopping his study to medical journals. Specifically, the Company paid Dr. Kuklo $356,242 in 2007, the year Dr. Kuklo sought publication of the study in two medical journals, and $249,772 in 2008, the year the study was published. Medtronic made both of these payments after the Company announced the settlement with the DOJ in July 2006. *The Wall Street Journal* subsequently reported on June 24, 2009 that Medtronic had received a subpoena from federal prosecutors about its payments to Dr. Kuklo.

138. In July 2009, Senator Grassley also publicly disclosed information demonstrating that Dr. Kuklo hid his financial relationship from Washington University and failed to disclose his financial ties in conflict of interest disclosure forms while he was conducting research related to Infuse. As revealed in documents provided by Washington University and reported in *The New York Times* and *The Wall Street Journal*, the Company financed two separate, unpublished studies that also examined the use of Infuse on Walter Reed patients with combat-related leg injuries while Dr. Kuklo was supposedly conducting research for the falsified study. At the time Washington

University approved the study protocols, Dr. Kuklo indicated on disclosure forms that he did not receive any payments from Medtronic when, in fact, Dr. Kuklo signed a contract with the Company shortly after joining the university faculty and had received payments from Medtronic for almost a year into his research. In mid-2007, after Dr. Kuklo disclosed to Washington University that he had received funding from Medtronic, the university's internal disclosure review board re-reviewed Dr. Kuklo's involvement in the Medtronic-sponsored studies and informed him he would have to reduce his personal financial interest with Medtronic to less than $10,000 per year or discontinue his involvement with the research. Dr. Kuklo opted to stop the two studies, which were closed in February 2008.

139. Dr. Kuklo was not the only Medtronic-funded surgeon at Washington University who failed to disclose the full extent of his financial ties to Medtronic under the university's conflicts of interest policies. A June 4, 2009 article published in the *St. Louis Beacon* revealed that university surgeon Dr. Daniel Riew, a Medtronic consultant who had earlier publicly defended Dr. Kuklo in an article in the *St. Louis Post Dispatch* when reports of the falsified Army study first surfaced, also failed to properly report significant payments from the Company. The article quoted a May 21, 2009 letter from Senator Grassley---who had requested information regarding consulting payments from both Medtronic and the university as part of the congressional inquiry into conflicts of interest in the medical device industry---which noted that the consulting payment amounts that Medtronic submitted to the Senator did not match those that Dr. Riew reported to the university. For example, according to Senator Grassley, while Dr. Riew reported to the university that he received less than $10,000 in 2006, "[i]n fact, Medtronic reported to me that there was not a single year from 2003 to 2007 for which Dr. Riew received less than $10,000. In fact, he received well over $10,000 in each of those years."

140. On June 20, 2009, the *Milwaukee Journal Sentinel* reported that in 2008, Medtronic paid Dr. Zdeblick $2 million in royalty payments and for eight days of consulting work, and Dr. Paul Anderson received $150,000 in Medtronic consulting fees for working just eight days---figures that were only recently disclosed under the University of Wisconsin's new conflict-of-interest disclosure rules.

141. On July 22, 2009, the *Wall Street Journal* reported that Dr. Jeffrey Wang lost his position as co-executive director of UCLA's Comprehensive Spine Center for failing to disclose that he was receiving consulting fees from Medtronic.

142. On July 29, 2009, the *Wall Street Journal* reported that Dr. Polly also failed to disclose payments he had received from Medtronic in connection with testimony before a Senate committee in 2006.

143. On August 19, 2009, the *Wall Street Journal* reported that Dr. Kuklo had "agreed to voluntary resign" from Washington University's Medical School as a result of the Army investigation that concluded that he had falsified data in the *Journal of Bone and Joint Surgery*.

144. The congressional inquiry and other negative publicity surrounding Medtronic's financial ties with surgeons involved with Infuse has also been accompanied by federal and state regulatory action. As the Company has admitted, the July 2008 FDA health warning, DOJ scrutiny and negative publicity surrounding Infuse have all contributed to declining sales of the product.

145. In Medtronic's Third Quarter 2009 financial results (the "3Q 2009 10-Q") filed with the SEC on March 4, 2009, the Company also disclosed that it had received a civil investigative demand from the Massachusetts Attorney General's Office requesting production of documents related to Infuse.

146. In addition to this new inquiry, the 3Q 2009 l0-Q indicated that sales of Infuse continued to lag as a result of "a public health notice from the FDA regarding the off-label use of

recombinant human bone morphogenic protein in the cervical spine that was issued in July 2008, a previously disclosed government investigation, negative newspaper stories, and a whistleblower lawsuit filed against a number of spine surgeons and distributors of INFUSE bone graft." Further, the Company specifically noted that the slight increase in overall growth in Infuse sales for the nine-month period ended January 23, 2009 was entirely "driven from net sales in the three months ended July 25, 2008" and prior to the materialization of the risks presented by Medtronic's undisclosed off-label marketing campaign.

147. Likewise, Medtronic disclosed in its fourth-quarter and full-year financial results for the 2009 fiscal year (ended April 24, 2009) filed with the SEC on June 23, 2009 (the "2009 10-K"), that sales of Infuse continued to suffer as a result of the negative publicity surrounding Medtronic's business practices, the risks to patient safety, and the governmental investigations into the Company's off-label promotion of Infuse:

> Biologics net sales for fiscal year 2009 were $840 million, an increase of 3 percent when compared to the prior fiscal year. This increase was primarily driven by worldwide net sales growth of INFUSE Bone Graft in the first quarter of fiscal year 2009. ***Net sales of INFUSE Bone Graft during the remainder of fiscal year 2009 were flat because of the negative impact of several external factors including: a public health notice from the FDA regarding off-label use of recombinant human bone morphogenic protein in the cervical spine that was issued in July 2008, a previously disclosed government investigation, negative newspaper stories and a whistleblower lawsuit filed against a number of spine surgeons and distributors of INFUSE Bone Graft.*** [Emphasis added.]

148. In the 2009 10-K, the Company further admitted that "[d]uring fiscal year 2009, the FDA issued a public health notice regarding use of bone morphogenetic protein in cervical procedures, which was received negatively by both physicians and payors. As a result, this negatively impacted the sales of our INFUSE Bone Graft in fiscal year 2009."

149. The filing also disclosed additional governmental investigations into Infuse. Specifically, the Company stated that it received a subpoena on May 21, 2009 from the United States Attorney's Office for the District of Massachusetts seeking documents related to Dr. Kuklo's

falsified study and "contracts, research grants, speaking and education programs, and payments for certain named physicians," and revealed that it received an administrative subpoena from the New Jersey Attorney General requesting "production of documents relating to the Company's clinical studies, its financial arrangements with certain physicians and health care providers, and clinical research done by certain physicians and health care providers."

G. The False and Misleading 2011 Proxy Statement

150. On July 15, 2011, Defendants Ellis, Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, Schuler, and Ishrak caused Medtronic to issue a definitive Proxy Statement which solicited Medtronic shareholders to vote at the 2011 annual meeting of stockholders (the "2011 Proxy Statement").

151. The 2011 Proxy Statement also included a Report of the Audit Committee, which stated:

> The Audit Committee represents and assists the Board of Directors in its oversight of the integrity of Medtronic's financial reporting. In particular, the Audit Committee reviews the independence, qualifications and performance of Medtronic's independent registered public accounting firm and the performance of its internal auditors. The Audit Committee also has responsibility for Medtronic's compliance with legal and regulatory requirements. As of the date of this report, the Audit Committee consisted of the five members listed below, each of whom is an independent director in accordance with SEC and New York Stock Exchange requirements and meets additional independence standards applicable to audit committee members. Denise M. O'Leary, David L. Calhoun, Shirley Ann Jackson, Ph.D., James T. Lenehan and Robert C. Pozen each qualifies as an "audit committee financial expert" within the meaning of that term as defined by the SEC pursuant to Section 407 of the Sarbanes-Oxley Act of 2002.
>
> Medtronic's management is responsible for preparing Medtronic's financial statements and the overall reporting process, including Medtronic's system of internal controls. The Audit Committee is directly responsible for the compensation, appointment and oversight of Medtronic's independent registered public accounting firm, PricewaterhouseCoopers LLP ("PricewaterhouseCoopers"), that reports directly to the Audit Committee. The independent registered public accounting firm is responsible for auditing the financial statements and expressing an opinion on the conformity of the audited financial statements with generally accepted accounting principles in the United States ("U.S. GAAP") and auditing the Company's internal control over financial reporting. The Audit Committee also meets privately in

separate executive sessions periodically with management, internal audit and representatives from Medtronic's independent registered public accounting firm.

In this context, the Audit Committee has held discussions with management and PricewaterhouseCoopers. Management represented to the Audit Committee that Medtronic's consolidated financial statements were prepared in accordance with U.S. GAAP, and the Audit Committee has reviewed and discussed the audited financial statements with management and PricewaterhouseCoopers.

PricewaterhouseCoopers has informed the Audit Committee that, in its opinion, the consolidated balance sheets and the related consolidated statements of earnings, shareholders' equity and cash flows that accompany Medtronic's 2011 Annual Report present fairly, in all material respects, the financial position of Medtronic and its subsidiaries at April 29, 2011 and April 30, 2010, and the results of Medtronic's operations and cash flows for each of the three fiscal years in the period ended April 29, 2011 are in conformity with U.S. GAAP.

The Audit Committee also has discussed with PricewaterhouseCoopers the matters required to be discussed by Statement on Auditing Standards No. 61 (Communication With Audit Committees), as amended, and requested any other relevant input from PricewaterhouseCoopers. PricewaterhouseCoopers provided to the Audit Committee, and the Audit Committee received, the written disclosures and letter required by applicable requirements of the Public Company Accounting Oversight Board regarding PricewaterhouseCoopers' communications with the audit committee concerning independence, and the Audit Committee discussed with PricewaterhouseCoopers their independence.

Based on the considerations above, the Audit Committee recommended to the Board of Directors, and the Board has approved, the inclusion of the audited financial statements in Medtronic's Annual Report on Form 10-K for fiscal year 2011 for filing with the Securities and Exchange Commission. The Audit Committee has selected PricewaterhouseCoopers as Medtronic's independent registered public accounting firm for fiscal year 2012. Audit and any permitted non-audit services provided to Medtronic by PricewaterhouseCoopers are pre-approved by the Audit Committee.

AUDIT COMMITTEE:

Denise M. O'Leary, Chair
David L. Calhoun
Shirley Ann Jackson, Ph.D.
James T. Lenehan
Robert C. Pozen

152. These statements in the 2011 Proxy Statement were false and misleading because they failed to disclose that Medtronic had continued to violate federal law by improperly promoting and marketing Infuse to doctors for off-label use. The statements were also false and misleading

because they failed to disclose that the Individual Defendants caused the Company to mislead shareholders about the source of Infuse's revenues.

153. Had the truth about Medtronic's improper promotion and marketing of Infuse been properly disclosed, the disclosures would have materially affected the shareholders' voting decisions with respect to the matters voted upon in the Proxy, including the re-election of Anderson, Calhoun, Dzau, Ishrak, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler at the 2011 Annual Meeting of Stockholders and the shareholders' voting decision as to the appointment of PricewaterhouseCoopers LLP as the Company's independent public accounting firm.

THE STOCK REPURCHASES

154. In October 2005, the Board of Directors authorized the repurchase of up to 40 million shares of the Company's common stock; in April 2006, the Board of Directors authorized the Company to repurchase up to 50 million shares; in June 2007, the Board of Directors authorized the repurchase of an additional 50 million shares of the Company's common stock.

155. While the Individual Defendants were issuing false and misleading statements about Infuse between November 2006 and November 2008, the Board caused the Company to repurchase a total of over ***$2.8 billion*** of its own stock.

156. The purchases of the Company's stock, however, were at artificially inflated prices as a result of the false and misleading statements, press releases, and filings with the SEC that failed to disclosed that (1) 85% Infuse's revenues were dependent upon off-label uses of the product; (2) off-label uses of Infuse were causing a significant and increasing number of medical complications to patients; and (3) the Company was engaging in an unlawful campaign to market and encourage off-label uses of the product in direct violation of the Corporate Integrity Agreement with the DOJ.

157. Medtronic's Board was well aware of the false and misleading statements during the entire repurchase period from November 2006 through November 2008. Medtronic's Board knew

about the whistleblower lawsuits, the $40 million settlement agreement with the DOJ, and the Company's illegal promotion of off-label uses for Medtronic's products. Indeed, Medtronic agreed in the CIA that its senior management would monitor Medtronic's activities related to marketing. The agreement was signed before the Relevant Period and thus the Board knew what was expected of them.

158. Despite the Board's knowledge of the true facts about the source of Infuse's revenues, the Board did not halt the Company's purchases and continued to allow the Company to purchase shares at artificially inflated prices. The Board's decision was not the product of a valid business judgment.

159. The following were the average prices paid for the Company's common stock:

Time Period	# of Shares	Ave. Price	Total Cost
12/30/06 – 01/26/07	749,000	$53.35	$39,959,150
01/29/07 – 04/27/07	11,729,874	$51.59	$605,144,200
04/28/07 – 07/27/07	10,000,000	$52.05	$520,500,000
07/28/07 – 10/26/07	7,900,000	$50.73	$400,767,000
10/27/07 – 01/25/08	11,500,000	$49.06	$564,190,000
01/28/08 – 02/22/08	1,719,900	$46.51	$79,950,690
04/25/08 – 07/25/08	3,400,000	$51.33	$174,522,000
07/26/08 – 10/24/08	9,500,000	$48.64	$462,080,000
TOTAL	**56,498,774**		**$2,847,113,040**

160. Under the Board's authorization, the Company bought back more than $2,847,113,040 worth of its shares at a weighted average price of $50.39. Tellingly, this weighted average price is substantially higher than Medtronic's share price of $31.60 on November 18, 2008 when its true business health was revealed.

161. Because the price of Medtronic's shares was artificially inflated by way of the Individual Defendants' concealment and misrepresentations, the Company materially overpaid for its

own stock. The stock purchases falsely signaled to Medtronic's shareholders and the public that the purchase of the Company's stock at those prices was the best use of Medtronic's cash. Thus, Defendants Collins, Hawkins, Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, Schuler, Bonsignore, Sprenger, and Brody breached their fiduciary duties and committed corporate waste by causing Medtronic to purchase its own shares at artificially inflated prices.

DUTIES OF THE INDIVIDUAL DEFENDANTS

A. Fiduciary Duties

162. By reason of their positions as officers, directors, and/or fiduciaries of Medtronic and because of their ability to control the business and corporate affairs of Medtronic, the Individual Defendants owed and owe the Company and its shareholders fiduciary obligations of trust, loyalty, good faith, and due care, and were and are required to use their utmost ability to control and manage Medtronic in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Medtronic and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit.

163. Each director and officer of the Company owes to Medtronic and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing. In addition, as officers and/or directors of a publicly held company, the Individual Defendants had a duty to promptly disseminate accurate and truthful information with regard to the Company's operations, performance, management, projections, and forecasts so that the market price of the Company's stock would be based on truthful and accurate information.

B. Audit Committee Duties

164. In addition to these duties, members of the Audit Committee owed specific duties, under the Audit Committee's Charter to review and approve quarterly and annual financial statements, earnings press releases, and the Company's internal controls over financial reporting. Some of the Audit Committee's responsibilities included:

1. Review the annual audited financial statements with management and the independent auditor, including the Company's disclosures under Management's Discussion and Analysis of Financial Condition and Results of Operations, significant issues and judgments regarding accounting and auditing principles and practices, and the effect of regulatory and accounting initiatives on the Company's financial statements, and recommend to the Board whether the financial statements should be included in the Form 10-K. The review of the annual audited financial statements also includes a review of any transactions as to which management obtained a letter pursuant to Statement on Auditing Standards No. 50.

2. Review and discuss with management and the independent auditor the Company's quarterly financial statements prior to filing the Form 10-Q, including the results of the independent auditor's review of them and the Company's disclosures under Management's Discussion and Analysis of Financial Condition and Results of Operations

3. Review major issues and changes to the Company's auditing and accounting principles and practices as suggested by the independent auditor, internal auditors or management, and analyses setting forth significant financial reporting issues and judgments, including analyses of the effects of alternative GAAP methods on the financial statements, and the effect of regulatory and accounting initiatives, as well as off-balance sheet structures, on the financial statements of the Company

4. Discuss policies with respect to risk assessment and risk management, including appropriate guidelines and policies to govern the process, as well as the Company's major financial and business risk exposures and the steps management has undertaken to monitor and control such exposures

C. The Code of Ethics For Senior Financial Officers

165. In addition, the Company's executive officers owed specific duties under the Company's Code of Ethics. Some of the duties included:

1. The CEO and all Senior Financial Officers are responsible for full, fair, accurate, timely and understandable disclosure in the reports and documents that the Company files with, or submits to, the Securities and Exchange Commission and in other public communications made by the Company. Accordingly, it is the responsibility of the CEO and each Senior Financial Officer promptly to bring to the attention of the General Counsel or the CEO any material information of which he or she may become aware that affects the disclosures made by the Company in its public filings.

2. The CEO and each Senior Financial Officer shall promptly bring to the attention of the General Counsel or CEO any information he or she may have concerning (a) significant deficiencies in the design or operation of internal controls which could adversely affect the Company's ability to record, process, summarize and report financial data or (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's financial reporting, disclosures or internal controls.

3. The CEO and each Senior Financial Officer shall act with honesty and integrity in the performance of his or her duties at the Company, shall comply with laws, rules and regulations of federal, state and local governments and other private and public regulatory agencies that affect the conduct of the Company's business and the Company's financial reporting.

4. The CEO and each Senior Financial Officer shall promptly bring to the attention of the General Counsel or the CEO any information he or she may have concerning evidence of a material violation of the securities or other laws, rules or regulations applicable to the Company and the operation of its business, by the Company or any agent thereof, or any violation of this Code of Ethics

D. Control, Access, and Authority

166. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Medtronic, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the public statements issued by Medtronic.

167. Because of their advisory, executive, managerial, and directorial positions with Medtronic, each of the Individual Defendants had access to adverse, non-public information about the financial condition, operations, and improper representations of Medtronic.

168. At all times relevant, each of the Individual Defendants was the agent of each of the other Individual Defendants and of Medtronic, and was at all times acting within the course and scope of such agency

E. Reasonable and Prudent Supervision

169. To discharge their duties, the officers and directors of Medtronic were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the financial affairs of the Company. By virtue of such duties, the officers and directors of Medtronic were required to, among other things:

(a) refrain from acting upon material inside corporate information to benefit themselves;

(b) ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the investing public;

(c) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(d) properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's financial results;

(e) remain informed as to how Medtronic conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiry in connection therewith, and take steps to correct such conditions or practices and make such disclosures as necessary to comply with securities laws; and

(f) ensure that Medtronic was operated in a diligent, honest, and prudent manner

in compliance with all applicable laws, rules, and regulations.

BREACHES OF DUTIES

170. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Medtronic, the absence of good faith on their part, and a reckless disregard for their duties to Medtronic and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to Medtronic. The conduct of the Individual Defendants who were also officers and/or directors of the Company have been ratified by the remaining Individual Defendants who collectively comprised all of Medtronic's Board.

171. The Individual Defendants each breached their duty of loyalty and good faith by causing the Company to issue false statements about Infuse and by misrepresenting the Company's financial results and prospects. In addition, as a result of the Individual Defendants' illegal actions and course of conduct, the Company is now the subject of a class action lawsuit that alleges violations of securities laws. As a result, Medtronic has expended, and will continue to expend, significant sums of money.

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

172. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their liability. The Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

173. During all relevant times, the Individual Defendants collectively and individually initiated a course of conduct that was designed to and did conceal that the Company was issuing false and misleading statements about the source of Infuse's revenues. In furtherance of this plan,

conspiracy, and course of conduct, the Individual Defendants collectively and individually took the actions set forth herein.

174. The Individual Defendants engaged in a conspiracy, common enterprise, and/or common course of conduct. During this time, the Individual Defendants caused the Company to issue false and misleading statements regarding Medtronic's financial results.

175. The purpose and effect of the Individual Defendants' conspiracy, common enterprise, and/or common course of conduct was, among other things, to: (a) disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment, and waste of corporate assets; and (b) disguise the Company's illegal marketing and promotion of off-label uses for Infuse.

176. The Individual Defendants accomplished their conspiracy, common enterprise, and/or common course of conduct by causing the Company to purposefully, recklessly, or negligently release improper statements. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants was a direct, necessary, and substantial participant in the conspiracy, common enterprise, and/or common course of conduct complained of herein.

177. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commissions of the wrongdoing complained of herein, each Individual Defendant acted with knowledge of the primary wrongdoing, substantially assisted the accomplishment of that wrongdoing, and was aware of his or her overall contribution to and furtherance of the wrongdoing.

DAMAGES TO MEDTRONIC

178. The Individual Defendants' wrongful conduct was the direct and proximate cause of damages Medtronic has suffered, and will suffer.

179. The Individual Defendants failed to disclose that the Company was issuing false and misleading statements about the source of Infuse's revenues. The improper statements and omissions have devastated Medtronic's credibility. Medtronic is now the subject of a class action lawsuit, alleging violations of securities laws in connection with the improper financial reporting, false statements, and material omissions. The Company will face substantial costs, expenses, and a potential adverse verdict in connection with that lawsuit. Additionally, the Company purchased over $2.8 billion of its own stock at artificially inflated prices under the Board's direction.

180. As a direct and proximate result of the Individual Defendants' actions as alleged above, Medtronic's market capitalization has been substantially damaged.

181. Further, as a direct and proximate result of the Individual Defendants' conduct, Medtronic has expended and will continue to expend significant sums of money. Such expenditures include, but are not limited to:

(a) costs incurred in investigating and defending Medtronic and certain officers in the class action lawsuit (which was certified as a class action by Order dated December 12, 2011), plus potentially hundreds of millions of dollars in settlement or to satisfy an adverse judgment;

(b) costs incurred from compensation and benefits paid to the Individual Defendants, which compensation was based at least in part on Medtronic's artificially-inflated stock price and inflated growth prospects;

(c) costs incurred from the loss of the Company's customers' confidence in Medtronic's products; and

(d) damages to the Company due to the false and misleading financial statements that the Individual Defendants caused the Company to file.

182. Moreover, these actions have irreparably damaged Medtronic's corporate image and goodwill. For at least the foreseeable future, Medtronic will suffer from what is known as the "liar's

discount," a term applied to the stocks of companies who have been implicated in illegal behavior and have misled the investing public, such that Medtronic's ability to raise equity capital or debt on favorable terms in the future is now impaired.

DERIVATIVE ALLEGATIONS

183. Plaintiff brings this action derivatively on behalf and for the benefit of the Company to remedy the wrongdoing alleged herein. Plaintiff brings this action for the benefit of Medtronic to redress injuries suffered, and yet to be suffered by Medtronic, as a direct and proximate result of the Individual Defendants' breaches of fiduciary duty, unjust enrichment, and waste of corporate assets. Medtronic is named in this action as a Nominal Defendant solely in a derivative capacity.

184. Plaintiff will fairly and adequately represent the interests of the Company and has retained competent counsel, experienced in derivative litigation, to enforce and prosecute this action.

185. This action is not a collusive one to confer jurisdiction on a court that it would not otherwise have.

186. Plaintiff did not make a demand on the Board to bring this action because such demand would be futile given the facts as alleged herein and, therefore, such a demand is excused.

187. Medtronic is controlled by its Board of Directors, which currently consists of the following twelve individuals: Anderson, Calhoun, Dzau, Ishrak, Jackson, non-defendant Michael O. Leavitt ("Leavitt"), Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler. Eleven of the twelve directors are named as defendants in this lawsuit and engaged in wrongful acts alleged herein. Thus, they are not disinterested and cannot exercise independent business judgment on the issue of whether Medtronic should prosecute this action. As a result, demand on Medtronic and its Board is futile and therefore excused.

A. Demand Is Futile As To Director Defendants Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler

188. Defendants Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler face a substantial likelihood of liability for disregarding the settlement agreement with the Department of Justice and allowing the Company to continue to illegally market Infuse for off-label uses. Indeed, Defendants Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler knew about the whistleblower lawsuits and the Company's $40 million settlement agreement with the DOJ in 2006. As part of that agreement, Medtronic agreed that its senior management would monitor Medtronic's activities related to its marketing of medical devices for off-label uses. The settlement agreement was signed before the Relevant Period so management knew what was expected of them. Thus, Defendants Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler either knew or recklessly disregarded that the Company was still promoting Infuse for off-label uses. Accordingly, Defendants Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler face a substantial likelihood of liability for breaching their fiduciary duties to the Company, rendering any demand upon them futile.

189. Defendants Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler also face a substantial likelihood of liability for causing the Company to issue false and misleading statements about the source of Infuse's revenues and the Company's compliance with the CIA. The false and misleading statements failed to disclose that (a) 85% Infuse's revenues were dependent upon off-label uses of the product; (b) off-label uses of Infuse were causing a significant and increasing number of medical complications to patients; and (c) the Company was engaging in an unlawful campaign to market and encourage off-label uses of the product in direct violation of the Corporate Integrity Agreement with the DOJ. As a result of their access to and review of internal corporate documents; conversations and connections with other corporate officers, employees and directors; and attendance at management and Board meetings,

Defendants Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler knew, or were reckless in not knowing that the Company was issuing false and misleading statements about Infuse, a product that represented 6% of Medtronic's total sales. Thus, Defendants Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler ignored the false statements in violation of their fiduciary duties and/or failed to take any action to correct the false statements. Accordingly, Defendants Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler face a substantial likelihood of liability for breaching their fiduciary duties to the Company, rendering any demand upon them futile.

190. Defendants Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler also face a substantial likelihood of liability for causing the Company to make the share repurchases. Defendants Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler caused the Company to repurchase over ***$2.8 billion*** of its own stock between November 2006 and November 2008. The purchases of the Company's stock, however, were at artificially inflated prices as a result of the false and misleading statements, press releases, and filings with the SEC. Each of these Defendants knew, but failed to act in the face of a known duty to act, and/or with gross negligence should have known that the Individual Defendants' statements were false and misleading, and that, as a result, the Company's stock was artificially inflated. Nonetheless, these Defendants authorized the Company's repurchase program. Thus, Defendants Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler are each subject to a substantial likelihood of liability. Accordingly, demand is futile as to these Defendants.

B. Demand Is Futile As To Audit Committee Defendants O'Leary, Calhoun, Jackson, Pozen, and Rosso

191. Defendants O'Leary, Calhoun, Jackson, Pozen and Rosso were members of Medtronic's Audit Committee when the false and misleading statements were being disseminated.

The Audit Committee is required to oversee the accuracy of Medtronic's financial reporting to insure the investing public is provided with accurate financial information. Despite these duties, the Audit Committee members issued and/or approved the false and misleading statements that failed to disclose that (a) 85% of Infuse's revenues were dependent upon off-label uses of the product; (b) off-label uses of Infuse were causing a significant and increasing number of medical complications to patients; and (c) the Company was engaging in an unlawful campaign to market and encourage off-label uses of the product in direct violation of the Corporate Integrity Agreement with the DOJ.

192. As a result of (a) their access to and review of internal corporate documents; (b) conversations and connections with other corporate officers, employees and directors; and (c) attendance at management and Board meetings, each of the members of the Audit Committee knew the adverse non-public information regarding Medtronic's business, operations, and management related to Infuse. Indeed, each of the members of the Audit Committee knew of the wrongdoing complained herein. Thus, Defendants O'Leary, Calhoun, Jackson, Pozen, and Rosso face a substantial likelihood of liability for their breaches of fiduciary duties, rendering any demand upon them futile.

C. Demand Is Futile As To Ishrak

193. Non-defendant Ishrak cannot render an independent decision because he is a high-ranking officer and his principal employment is with Medtronic. He received and continues to receive substantial monetary compensation and other benefits through his employment with Medtronic. For instance, the former CEO, Hawkins, received total compensation of over $9 million every year since 2009. Thus, Ishrak is expected to receive similar total compensation for serving as an executive officer of the Company. According to relevant portions of the Company's 2012 proxy statement, Ishrak is not an independent director pursuant to the requirements of the listing standards

of the NYSE. Further, Ishrak signed and approved the false and misleading 2011 Proxy Statement. Thus, demand is futile as to Ishrak.

D. Demand Is Futile As To All Of The Director Defendants For Additional Reasons

194. If Medtronic's officers and directors are protected against personal liability for their acts of mismanagement, abuse of control, and breaches of fiduciary duties alleged in this Complaint by Directors and Officers Liability Insurance ("D&O Insurance"), they caused the Company to purchase that insurance for their protection with corporate funds, *i.e.*, monies belonging to the shareholders. However, Plaintiff is informed and believes that the D&O Insurance policies covering the Individual Defendants in this case contain provisions that eliminate coverage for any action brought directly by Medtronic against the Individual Defendants, known as the "insured versus insured exclusion." As a result, if the Board of Directors were to sue themselves or certain of the officers of Medtronic, there would be no D&O Insurance protection, and thus, this is a further reason why they will not bring such a suit. On the other hand, if the suit is brought derivatively, as this action is brought, such insurance coverage exists and will provide a basis for the Company to effectuate recovery. Therefore, the Board of Directors cannot be expected to file the claims asserted in this derivative lawsuit because such claims would not be covered under the Company's D&O insurance policy.

195. Under the factual circumstances described herein, the Individual Defendants are more interested in protecting themselves than they are in protecting Medtronic by prosecuting this action. Therefore, demand on Medtronic and its Board is futile and is excused.

196. Medtronic has been and will continue to be exposed to significant losses due to the Individual Defendants' wrongdoing. Yet, the Board of Directors has not filed any lawsuits against themselves or others who were responsible for the wrongful conduct. Thus, the directors are

breaching their fiduciary duties to the Company and face a sufficiently substantial likelihood of liability for their breaches, rendering any demand upon them futile

COUNT I
Derivative Claim Against Defendants Anderson, Calhoun, Dzau, Ishrak, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler for Violation of Section 14(a) of the Exchange Act.

197. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

198. Defendants Anderson, Calhoun, Dzau, Ishrak, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, and Schuler who were Medtronic directors at the time, issued, caused to be issued, and participated in the issuance of materially false and misleading written statements and material omissions to shareholders that were contained in the Company's 2011 Proxy Statement. The 2011 Proxy Statement soliciting materials failed to disclose to the Company's shareholders that these Defendants had caused the Company to file materially false and misleading statements about the source of Infuse's revenues and that the Company was improperly promoting and marketing Infuse for off-label uses to doctors. By reasons of the conduct alleged herein, these Defendants who caused the issuance of the 2011 Proxy Statement violated Section 14(a) of the Exchange Act. As a direct and proximate result of these Defendants' wrongful conduct, the Company misled and/or deceived its shareholders by falsely portraying the operations of the Company.

199. Plaintiff, on behalf of the Company, thereby seeks relief for damages inflicted upon the Company in connection with the misleading and incomplete proxy materials. Medtronic is entitled to recover damages to compensate the Company for all damages resulting from the Defendants' acts and omissions in violation of Rule 14a-9.

COUNT II
Breach of Fiduciary Duty Against All Individual Defendants

200. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

201. The Individual Defendants owed and owe Medtronic fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed and owe Medtronic the highest obligation of good faith, fair dealing, loyalty, due care, reasonable inquiry, oversight and supervision.

202. The Individual Defendants violated and breached their fiduciary duties of good faith, fair dealing, loyalty, and due care.

203. The Individual Defendants each knowingly, recklessly or negligently signed or approved the issuance of false and misleading statements and allowed the Company to market Infuse for off-label purposes. These actions could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

204. As a direct and proximate result of these Individual Defendants' failure to perform their fiduciary obligations, Medtronic has sustained significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

205. Plaintiff, on behalf of Medtronic, has no adequate remedy at law.

COUNT III
Against Defendants Hawkins, Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, Schuler, Bonsignore, Bordy, and Sprenger for Breach of Fiduciary Duty for Authorizing the Company's Stock Purchases

206. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

207. The wrongful conduct alleged regarding the issuance of false and misleading statements, was continuous, connected, and was on-going throughout the applicable time period. It resulted in continuous, connected, and on-going harm to the Company.

208. Defendants Hawkins, Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, Schuler, Bonsignore, Brody, and Sprenger owed and owe Medtronic fiduciary obligations. By reason of their fiduciary relationships, these Defendants owed and owe Medtronic the highest obligation of loyalty, fair dealing, and good faith.

209. Defendants Hawkins, Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, Schuler, Bonsignore, Brody, and Sprenger violated and breached their fiduciary duty by knowingly, or with conscious disregard of their duties, authorizing Medtronic's stock repurchase plan and approving the Company's purchases under the stock repurchase plan while Medtronic's share price was artificially inflated as a result of the false and misleading statements. Medtronic repurchased 56,498,774 shares of its own stock on the open market, for a total cost to Medtronic of $2,847,113,040.

210. The wrongful conduct of Defendants Hawkins, Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, Schuler, Bonsignore, Brody, and Sprenger could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

211. As a direct and proximate result of these Defendants' failure to perform their fiduciary obligations, Medtronic has sustained significant damages. As a result of the misconduct alleged herein, Defendants Hawkins, Anderson, Calhoun, Dzau, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso, Schuler, Bonsignore, Brody, and Sprenger are liable to the Company.

COUNT IV
Waste of Corporate Assets Against All Individual Defendants

212. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

213. The wrongful conduct alleged regarding the issuance of false and misleading statements was continuous, connected, and on-going throughout the applicable time period. It resulted in continuous, connected, and on-going harm to the Company.

214. As a result of the misconduct described above, the Individual Defendants have caused Medtronic to incur substantial legal liability as the Company will incur significant legal costs defending itself as a result of the Individual Defendants' misconduct and unlawful actions.

215. Additionally, the Company purchased over $2.8 billion of its own stock at artificially inflated prices.

216. As a result of the waste of corporate assets, the Individual Defendants are liable to the Company.

217. Plaintiff, on behalf of Medtronic, has no adequate remedy at law.

COUNT V
Unjust Enrichment Against the Individual Defendants

218. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

219. The Individual Defendants were unjustly enriched at the expense of the Company by receiving incentive compensation based on the stock performance of Medtronic.

220. To prevent the Individual Defendants' unjust enrichment, the Court should order these Individual Defendants to disgorge to the Company all the proceeds they received from their wrongful conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of Medtronic, prays for relief and judgment as follows:

A. A determination that this suit is a proper derivative action and certifying Plaintiff as an appropriate representative of Medtronic for this action;

B. A declaration that each of the Defendants breached his or her fiduciary duties to Medtronic and violated Section 14(a) of the Exchange Act;

C. A determination and award to Medtronic for the damages sustained by it as a result of the violations set forth above from each of the Defendants, jointly and severally, together with interest thereon;

D. A declaration that the Company must take all necessary actions to reform and improve its corporate governance and internal procedures to protect the Company and its shareholders from a repeat of the damaging events described in this Complaint, including but not limited to, adopting the following remedial measures:

1. Strengthening the Board's supervision to ensure the Board accurately discloses the Company's true business prospects;
2. Allowing the Company's shareholders to nominate at least two new candidates for election to the Board; and
3. Modifying the Company's share repurchase program.

F. An award to Plaintiff for the costs and disbursements of this action, including reasonable fees and costs to Plaintiff's attorneys and experts; and

G. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff demands a trial by jury.

Dated: March 12, 2012

REINHARDT WENDORF & BLANCHFIELD

s/Garrett D. Blanchfield, Jr.

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Counsel for Plaintiff

VERIFICATION

I, Charlotte Kococinski, verify that I am a shareholder of Medtronic, Inc. (the "Company"), and am ready, willing, and able to pursue this action in the hope of improving the Company and recovering damages for the Company caused by the defendants' conduct. I have reviewed the allegations made in this Shareholder Derivative Complaint (the "Complaint"). As to those allegations of which I have personal knowledge, I believe them to be true; as to those allegations of which I lack personal knowledge, I rely upon my counsel and counsel's investigation, and believe them to be true. Having received a copy of the Complaint and reviewed it with counsel, I authorize its filing.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated:

3/7/12

Charlotte A Kokocinski

Charlotte Kokocinski